Exhibit B

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Page 1
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 2.
                                    : SUPERIOR COURT OF
                                    : NEW JERSEY
 3
     IN RE:
                                    : LAW DIVISION -
     PELVIC MESH/GYNECARE
                                   : ATLANTIC COUNTY
     LITIGATION
 4
                                    : MASTER CASE 6341-10
 5
     (GENERAL, GROSS, WICKER)
                                    : CASE NO. 291 CT
 6
       CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF
 7
                        CONFIDENTIALITY
 8
 9
                   Monday, November 5, 2012
10
11
               Transcript of the deposition of ANNE M.
12
     WEBER, M.D., M.S., called for examination in the
     above-captioned matter, said deposition taken
13
14
     pursuant to Superior Court Rules of Practice and
     Procedure by and before Kimberly A. Overwise, a
15
16
     Certified Realtime Reporter, Registered Professional
17
     Reporter, Certified Court Reporter, and Notary
18
     Public, at Mazie, Slater, Katz & Freeman, 103
     Eisenhower Parkway, 2nd Floor, Roseland, New Jersey,
19
20
     on the above date, beginning at 9:41 a.m.
21
22
                  GOLKOW TECHNOLOGIES, INC.
              877.370.3377 ph | 917.591.5672 fax
23
                       deps@golkow.com
24
25
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	· ————————————————————————————————————	Page 2			Page 4
1 2 2 3 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	APPEARANCES: MAZIE SLATER KATZ & FREEMAN, LLC BY: ADAM M. SLATER, ESQ. CHERYLL A. CALDERON, ESQ. 103 Eisenhower Parkway, 2nd Floor Roseland, NJ 07068 973-228-9898 aslater@mskf.net ccalderon@mskf.net Counsel for Plaintiffs BERNSTEIN LIEBHARD, LLP BY: JEFFREY S. GRAND, ESQ. 10 E. 40th Street, 22nd Floor New York, NY 10016 212-779-1414 grand@bernlieb.com Counsel for Plaintiffs BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC BY: CHRISTY D. JONES, ESQ. 1020 Highland Colony Parkway, Suite 1400 Ridgeland, MS 39157 601-948-5711 christy.jones@butlersnow.com Counsel for Johnson & Johnson and Ethicon BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC BY: NILS B. (BURT) SNELL, ESQ. 500 Office Center Drive, Suite 400 Fort Washington, PA 19034 267-513-1884 burt.snell@butlersnow.com Counsel for Johnson & Johnson and Ethicon SILLS CUMMIS & GROSS, P.C. BY: WILLIAM R. STUART, ESQ. One Riverfront Plaza Newark, NJ 07102 973-643-0700 wstuart@sillscummis.com Counsel for Caldera Medical, Inc., and Synovis	raye 2	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	I N D E X WITNESS: Page ANNE M. WEBER, M.D., M.S. By Ms. Jones	raye 4
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	APPEARANCES VIA PHONE AND STREAM: KLINE & SPECTER, P.C. BY: ROGER CAMERON, ESQ. 1525 Locust Street, 19th Floor Philadelphia, PA 19102 215-772-1000 roger.cameron@KlineSpecter.com Counsel for Plaintiffs	Page 3	1 2 3 4 5 6 7 8 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	DEPOSITION SUPPORT INDEX Direction to Witness Not to Answer Page Line 65	Page 5

		Page 6		Page 8
1	CONFIDENTIAL DESIGNATION INDEX		1	ANNE M. WEBER, M.D., M.S., after
			2	having been duly sworn, was examined and
2	No Confidential Designations Colonitted for		3	testified as follows:
3	No Confidential Designations Submitted for		4	
4	Volume I.		5	EXAMINATION
5			6	BY MS. JONES:
6 7			7	Q Doctor, would you state your name and
8			8	address for the record, please?
9			9	A My name is Anne Margaret Weber. My
10			10	address is 5626 Sharon Drive in Glen Arm two
11			11	words with a capital A Maryland 21058.
12			12	Q And is that your home address?
13			13	A Yes.
14			14	Q Do you have a separate business address at
15			15	this point?
16			16	A No.
17			17	Q And are you currently employed, Doctor?
18			18	A I'm employed in consulting.
19			19	Q Do you have a separate consulting company?
20			20	A No. I'm not personally incorporated.
21			21	Q When you say that you are engaged in
22			22 23	consulting, what kind of consulting are you engaged in?
23 24			24	A Consulting on this case.
25			25	Q And that would be in litigation involving
23			23	Q And that would be in higherent involving
		Page 7		Page 9
1	CONFIDENTIAL DESIGNATION INDEX	Page 7	1	pelvic mesh; correct?
	CONFIDENTIAL DESIGNATION INDEX	Page 7	2	pelvic mesh; correct? A That's this case, yes.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	CONFIDENTIAL DESIGNATION INDEX	Page 7	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	pelvic mesh; correct? A That's this case, yes. Q And can you tell me when you were first retained in this case? A I began working in February of 2010. Q By whom were you first contacted? A I believe it was by Beth Baldinger of Adam's firm. Q And approximately when was that? A I believe it was in the fall of 2009. Q And you said that you did not start working on this case until the spring of 2010? A February, yes. Q What happened in that interim between being contacted and actually starting working on this case? A At some time later Adam contacted me and we talked in more detail about exactly what the work would involve and to make the specific arrangements to go ahead. Q And what was your understanding about the work involved?

		I	
	Page 10		Page 12
1	there a specific product that you were asked to	1	in a case in which you were a litigant. Can you
2	evaluate?	2	tell me about that, please?
3	A The Prolift® product and procedure.	3	A Yes. A patient I had seen once while I
4	Q And was it just the original Prolift® or	4	was on faculty at the Cleveland Clinic brought a
5	was it Prolift+M® as well?	5	claim against the clinic.
6	A Just the original Prolift®. Q And has that remained your charge	6 7	Q And were you named as a party? A Yes.
7 8	Q And has that remained your charge throughout until today?	8	A Yes. Q Presumably that was a medical malpractice
9	A Yes.	9	claim?
10	Q Have you previously given a deposition?	10	A I believe so.
11	A Yes.	11	Q Did that case go to trial?
12	Q On how many occasions?	12	A It was dismissed.
13	A Twice.	13	Q Do you remember the name of the plaintiff?
14	Q Can you tell me in what context? Was that	14	A No.
15	as a consultant, an expert witness?	15	Q About when did you give that deposition?
16	A One of the cases I served as an expert	16	A I believe it was in around 2002.
17	witness for the defense and in the other case I was	17	Q It was after you had left the Cleveland
18	one of the litigants.	18	Clinic then?
19	Q Let's talk about when you served as an	19	A Yes.
20	expert witness for the defense. What type of case	20	Q And what were the allegations in that
21	was that?	21	case?
22	A Medical malpractice.	22	A This woman subsequently developed
23	Q Do you remember the style of the case or	23	infertility and believed that she should have been
24	the names of the parties involved?	24	offered egg retrieval as an option in her past, at
25	A The doctor was Dr. Neil Jackson. I don't	25	which time it wasn't even feasible.
I			
	Page 11		Page 13
1	remember the plaintiff.	1	Q When you say she subsequently developed
2	remember the plaintiff. Q Where was the case pending?	2	Q When you say she subsequently developed infertility, did she develop infertility as a result
2	remember the plaintiff. Q Where was the case pending? A The doctor was from Providence. The case	2 3	Q When you say she subsequently developed infertility, did she develop infertility as a result of a procedure or was the claim simply that she had
2 3 4	remember the plaintiff. Q Where was the case pending? A The doctor was from Providence. The case was in Newport, Rhode Island.	2 3 4	Q When you say she subsequently developed infertility, did she develop infertility as a result of a procedure or was the claim simply that she had not been given appropriate counseling and
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2 3 4 5 6 7	remember the plaintiff. Q Where was the case pending? A The doctor was from Providence. The case was in Newport, Rhode Island. Q Did you actually testify at trial or just by deposition? A Yes, I testified at trial.	2 3 4 5 6 7	Q When you say she subsequently developed infertility, did she develop infertility as a result of a procedure or was the claim simply that she had not been given appropriate counseling and alternatives when being treated for infertility? A I didn't treat her for infertility. I provided her with routine gynecologic care. And she
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Page 14 Page 16 article, are you required to conduct a search of the 1 Yes. 1 Q Tell me what that is. medical literature or are you instead furnished with 2 2 3 A I receive disability for my medical literature and asked to prepare the review on 3 4 condition. And we have investments --4 previously identified literature? 5 MR. SLATER: She's not talking about 5 A I search the literature myself and 6 identify what seems relevant to me to comment on. 6 your personal income. 7 BY MS. JONES: 7 Q Let me see if I can go back. I got a 8 O I don't really want to go into your --8 little bit distracted here. Let me say, Doctor, you're standing. And before you came in, Mr. Slater 9 A Okav. advised that you intended to stand for portions of 10 Q I don't want to go into your personal 10 11 investment history and income and so forth. I 11 the day. And I take it that that is because of a didn't mean to pry in the sense of that. I'm just physical condition that's more comfortable for you? 12 12 trying to figure out other --13 13 A Correct. 14 MR. SLATER: Work that you do for 14 0 Let me just say although we're on a relatively tight schedule here, I want you to know 15 third parties. 15 if at any time you need to take a break or go walk 16 THE WITNESS: Yes. 16 around the block, if you'll just let me know, I'll 17 BY MS. JONES: 17 Q -- work that you do for anyone else. 18 18 be glad to accommodate it and do whatever we can. A Okay. I provide editorial reviews for the 19 Okay? 19 20 International Academy of Pelvic Surgery. 20 Α Thank you. Q And are you compensated for that? 21 By the same token, if at any time you 21 don't understand my questions or you need me to 22 22 Α Yes. repeat something, if you'll stop me and ask me, I'll 23 Q Are you on a salary --23 24 24 see what I can do to accommodate that. Α No. 25 25 A Yes. Q -- with them? Page 15 Page 17 And can you just tell me how you are 1 Q You indicated earlier that you have 1 2 disability income. Can you just tell me how long compensated? 2 3 A It's \$250 an hour. 3 you have been disabled? And approximately how much time do you 4 4 A I left my surgical practice in 2004. 5 spend working with the International Academy of 5 Q And I don't want to pry, but can you just 6 Pelvic Surgery? briefly describe for me was it your physical 6 7 A I would say eight hours a month. 7 condition that led to you leaving your surgical 8 Q I gather it would vary from time to time 8 practice? 9 depending upon what you're doing? 9 Α Yes. A Well, I typically provide a monthly series 10 Q Can you just give me an overview or just a 10 of reviews of current medical literature. generalization of what that disability is? 11 11 12 Q I'm sorry. Would you say that again, 12 MR. SLATER: Let's go off the record 13 please? 13 for a second. A I typically provide a review of the (Discussion off the record.) 14 14 15 current medical literature. 15 BY MS. JONES: Q And the current medical literature, is Q What I've just asked, Doctor, is if you 16 16 can just tell me what about your physical condition that limited to certain topics? 17 17 18 A To urogynecology. 18 led to your disability from a surgical practice or Q And within the realm of urogynecology, is affected your surgical practice. 19 19 it limited to any more specialized area, stress 20 20

A I have a pain condition that limits my ability to perform the kind of surgery I was trained to perform.

Q Does it limit your ability specifically to perform pelvic floor repair surgery?

A That is the surgery I was specifically

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urinary incontinence or pelvic organ prolapse or any

other more specific area, or does it cover the whole

A The broad spectrum of urogynecology.

And when you say you provide the review

broad spectrum of urogynecology?

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Page 18 Page 20 1 trained to perform. 1 BY MS. JONES: 2 Q I understand that. I guess what I'm 2 Q If we're talking about the different types 3 asking is would it affect your ability to do other 3 of surgeries that you were performing in 2004, were 4 types of surgery? you performing, for example, abdominal 4 5 5 A I would presume so. sacrocolpopexies? Q You said that you left your surgical 6 A Yes. 6 7 practice in 2004; is that right? 7 And how long as a general matter would it 8 8 A Correct. take you to perform that surgery? 9 Was there a period of time before 2004 9 A It depends on the patient. Q 10 where you gradually began to reduce the number of 10 Q I understand that, but give me an idea. surgeries that you performed as a result of this 11 Would it be three or four hours? 11 condition? 12 A I would say two to four hours. 12 O Were you also performing, for example, 13 13 A No. sling surgeries to repair urinary incontinence? 14 Q Did this condition have a precipitous 14 15 onset? 15 Α Yes. 16 THE WITNESS: Adam? 16 Q And how long would those procedures take? It would be very unusual for me to perform 17 MR. SLATER: If you don't --17 18 THE WITNESS: I just don't 18 a sling in an isolated -- as an isolated procedure. This would be almost always in the context of a understand --19 19 20 MR. SLATER: Let's go off the record. 20 concomitant prolapse operation. I object to the question. 21 Q Other than the abdominal sacrocolpopexies, 21 22 (Discussion off the record.) 22 what types of other prolapse surgeries were you performing at that time? 23 MR. SLATER: I have a hard time with 23 that because obviously Dr. Weber doesn't want to 24 A For apical prolapse, uterosacral ligament 24 talk in detail about her physical medical condition. 25 suspension. For anterior and posterior prolapse, 25 Page 19 Page 21 And, you know, she's trying to give you what she 1 anterior and posterior colporrhaphy. 1 can, but she's obviously uncomfortable talking about 2 2 O How long did it take you to perform an 3 3 anterior colporrhaphy, for example? this. Again, it's very uncommon to have an 4 MS. JONES: All I really want to know 4 5 is how it affected the surgical practice. 5 isolated procedure like that. Very few women come MR. SLATER: So why don't we just go in with one aspect of a pelvic floor disorder, at 6 6 least to my practice. 7 with that question: What was it about your 7 8 8 condition that impacted your ability to perform your Q Did all of the surgeries that you 9 surgical practice? 9 performed, whether it's the abdominal sacrocolpopexy Are you okay with that? Because that 10 or a TVT® sling procedure, equally affect your 10 I think is a relevant question. condition? 11 11 THE WITNESS: It exacerbated my pain 12 My surgical practice consisted of a day of 12 surgery. So when I was going to surgery, it was for 13 condition. 13 14 MR. SLATER: Can I help you for a 14 the day. 15 15 Q How many days a week did you operate? second? 16 Are you talking about the physical 16 Α One. 17 requirements --17 For what period of time would that have been true? This was when you were in Pittsburgh; 18 THE WITNESS: Yes. 18 19 MR. SLATER: -- on your body of 19 correct? performing surgery in the operating room --20 20 A Correct. I expected you were referring to that, although that was also t rue for my clinical 21 THE WITNESS: Yes. It's very 21 practice in Cleveland unless I needed extra time. 22 22 demanding. MR. SLATER: -- that would exacerbate 23 Typically one day a week. 23 24 your condition? 24 Q So from the time you were in Cleveland 25 25 through the time you were in Pittsburgh, that was THE WITNESS: Yes.

your typical practice to have one day a week set 2 aside for surgery? 3 A Correct. 4 Q Let me go back and ask you about the case 5 where you testified. I think you told me the 6 doctor's name was Neil Jackson? 7 A Yes. 8 Q When was that testimony? 9 A I don't remember exactly. I believe it 10 was somewhere in the range of seven to ten years 11 ago. 12 Q So sometime between 2002 and 2005 roughly? 13 A I think that's right. 14 Q Were you living in Pittsburgh at the time? 15 A Yes. 16 Q Were you still on staff in Pittsburgh? 17 A Yes. 18 Q Incidentally, when you ceased your 18 surgical practice in 2004, did you remain on staff 20 at the institution? 21 A Yes. 22 Q And am I correct that you did so until 23 2006? 24 A Yes. 25 Q Can you tell me what you did from 2004 to 2				
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7	5	where you testified. I think you told me the	5	Q And then consult with the patients about
8	6	doctor's name was Neil Jackson?	6	the appropriate treatment for whatever condition
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1	A Yes. Q That would be one of the standard risks	1	A Yes.
2	recognized by the medical community and known in the	2	Q Was that early 2004 or late 2004? A I believe it was in the fall.
4	context of doing virtually any type of pelvic	4	Q When was the last time that you were
5	surgery; correct?	5	actually engaged in the practice of medicine?
6	MR. SLATER: Objection to the form.	6	A At the end of 2005.
7	You can answer.	7	Q And so in that interim between the fall of
8	THE WITNESS: What do you mean by	8	2004 and the end of 2005, that would have been the
9	"standard"?	9	time period in which you were seeing patients in an
10	BY MS. JONES:	10	office setting with a fellow?
11	Q To be honest, I don't even remember how I	11	A Correct.
12	used the word "standard" so let me rephrase the	12	Q Do I understand correctly that you have
13	question.	13	not actually examined a patient since the end of
14	Voiding dysfunction would be a recognized	14	2005?
15	complication of most pelvic surgeries; correct?	15	A Correct.
16	MR. SLATER: Objection to the form.	16	Q Have you provided any type of consultation
17	You can answer.	17	to a patient since the end of 2005?
18	THE WITNESS: There are gradations of	18	A No.
19	voiding dysfunction that are very important to	19	Q And that would include not written any
20	differentiate between the different types of	20	prescriptions or advising or consulting about
21	surgery.	21	surgery or a medical condition?
22	BY MS. JONES:	22	A Correct.
23	Q Can you explain that to me?	23	Q I take it that you are not currently on
24	A By "gradations" I mean a spectrum ranging	24	staff at any hospital?
25	from mild to severe.	25	A Correct.
	Page 27		Page 29
1	Q And that spectrum ranging from mild to	1	Q And have not been since 2005?
2	severe may be associated with a variety of pelvic	2	A I remained at Magee-Womens Hospital at the
3	surgeries; correct?	3	University of Pittsburgh until May 2006.
4	A Yes.	4	Q So during that six-month period from the
5	Q And that is true whether or not those	5	end of 2005 until mid-2006, you would have remained
6	surgeries involve the use of mesh?	6	on staff there?
7	A I don't agree with that.	7	A Correct.
8	Q You don't agree that voiding dysfunction	8	Q But that would have been the only place
9	is a complication of surgeries that do not use mesh?	9	that you had privileges at that point in time?
10	MR. SLATER: Objection to the form.	10	A Correct.
11	You can answer.	11	Q And since that point in time you have not
12	THE WITNESS: That wasn't what I	12	had privileges elsewhere?
13	understood you to ask me.	13	A Correct.
14 15	BY MS. JONES:	14 15	Q And I take it that obviously at some time you moved from Pittsburgh back to Maryland?
16	Q Well, that's my question.A Could you repeat the question?	16	A Correct.
17	Q Sure. Is voiding dysfunction a recognized	17	Q When was that?
18	complication of pelvic surgeries that do not use	18	A That was in June of this year.
19	mesh?	19	Q June of 2012?
20	MR. SLATER: Objection to the form.	20	A Yes.
21	You can answer.	21	Q Did you remain in Pittsburgh in that
22	THE WITNESS: Yes.	22	interim?
23	BY MS. JONES:	23	A Yes.
	Q You said that you last performed surgery	24	Q What prompted your move to Maryland this
24			
24 25	in 2004; am I right?	25	year?

Page 30 Page 32 My husband has a new job. of appreciate your CV, as the program director 1 1 2 Your husband's not a medical doctor, is there, you kind of were the coordinator of certain 3 he? 3 clinical trials done by the network? 4 4 A No. A Not the coordinator. We had a data 5 Q You told us, Doctor, that you were first 5 coordinating center. That was their job. I was the contacted in the fall of 2009 about this litigation? 6 6 program director. 7 A I believe that's correct. 7 Q Well, tell me what that means as program 8 Q And that you thought you actually began 8 director. What did you do? working on the case in February 2010? 9 9 A Well, I ran the network. So I organized 10 A Yes. 10 and led the meetings that we held initially monthly 11 Q When you say that you began working on the 11 and then quarterly. I worked with the investigators case in February of 2010, what does that mean? What in designing and -- obviously they were performing 12 12 did you begin doing? the trials at their sites, but the data coming in, 13 13 A I began to review the Ethicon documents. the adverse events for different trials, we had 14 14 Q And those were all documents that would safety committees consisting of investigators and 15 15 have been sent to you by plaintiffs' counsel? members of the data coordinating center and myself. 16 16 17 A Yes. Shall I go on? 17 18 Q Prior to beginning review of those 18 Q Well, I'm going to come back to that. Let documents, had you ever reviewed the internal me see if I can stick with the adverse experience 19 19 20 documents of any device manufacturer? 20 reports that we were talking about. In that context 21 you would see adverse experience reports that were 21 22 O Or any drug manufacturer? 22 adverse events that took place in the context of the clinical trials; correct? 23 Α 23 24 Q I take it that you have not been a 24 Correct. Α 25 consultant to any drug or device manufacturer; is 25 Q And those reports that you received in the Page 31 Page 33 that correct? 1 context of a clinical trial might or might not have 1 2 2 anything to do with a device; correct? A That is correct. 3 3 A Correct. Q And that you have not been engaged in the determination as to whether or not a 510(k) is Can you tell me what trials were conducted 4 4 0 5 necessary to be filed; is that correct? 5 by the network that involved the use of a device? 6 6 A We performed a placebo-controlled trial A Yes. using a drug product, which is Botox, and in that 7 7 O That you've not before being engaged by plaintiffs' counsel in this litigation ever prepared context reviewing the adverse events that were 8 8 9 a 510(k)? 9 submitted to the FDA and to the manufacturer. A That is correct. 10 Q Any other product that you reviewed the 10 Before being engaged in this litigation, adverse events for? 11 11 12 had you ever reviewed a 510(k)? 12 Α A No. 13 13 Q No devices that you reviewed the adverse 14 Before being engaged in this litigation, 14 events for? 15 had you ever reviewed any of the different analyses 15 Α Correct. done, such as the failure mode evaluation analysis And I take it that you have never had a 16 16 or device design safety analysis, on any product? position where you actually went in and examined the 17 17 18 A No. 18 documents or database of a device manufacturer's adverse experience reports? 19 Q Had you ever reviewed any adverse 19 experience reports to the manufacturer? 20 A Correct. 20 21 A Yes. 21 And I take it that prior to being engaged

9 (Pages 30 to 33)

in this litigation, there's never been a time at

which you were in a position where you had to

determine whether or not an adverse event was

reportable to the FDA under the device regulations?

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Q In what capacity?

pelvic floor disorders network.

When I was the program director of the

Q I want to come back to this, but as I kind

Page 34 Page 36 That's correct. erosions that the investigators wondered whether 1 1 2 Prior to becoming involved in this 2 this was a particular combination of mesh with a 3 litigation, did you ever have an occasion to examine 3 particular combination of sutures. So we were 4 the MAUDE database of the FDA? 4 looking to the MAUDE database to see if we could 5 5 Α Yes. gather any information if anyone else's experience 6 6 had indicated that. 0 In what context? 7 In the context of experiences that we had 7 Q Can you tell me what types of sutures were 8 8 related to another trial we were running, which was being used? abdominal sacrocolpopexy, in terms of mesh and 9 9 A I don't remember. 10 suture complications. 10 Q Was there a particular type of mesh that 11 O And when was that? 11 was being used? Perhaps in 2005-2006. 12 12 A I don't remember. 13 Q Let me just put it into context. Were you 13 Do you remember whether the protocol for the trial required the use of a particular mesh in still at the Kerry Magee Hospital at the time? 14 14 A Magee-Womens Hospital. 15 15 the surgery? Q I'm sorry. A No, it did not. 16 16 A As I told you, I left Magee-Womens O So you might have had surgical meshes used 17 17 18 Hospital in May 2006, so chances are. 18 or manufactured by several different manufacturers? Q Well, I mean, I was trying to help you see That is possible. 19 19 if you could put dates around it a little bit. 20 20 Q And presumably they could also be That's --21 21 different types of meshes, partially absorbable, 22 A It doesn't --22 nonabsorbable? 23 It helps me sometimes to remember where I 23 A No. I believe the protocol required Q nonabsorbable mesh. 24 was when something happened in order to put a date 24 around it. That's the only reason I was asking. 25 25 Q Was that the CARE study? Page 35 Page 37 A My work at NIH was continuous. So, no, 1 Α Yes. 1 2 I'm sorry, that doesn't help me. 2 Do you remember what the exposure rate 0 Q Okay. Can you tell me about that trial 3 3 was? that involved abdominal sacrocolpopexy? Did I 4 4 A Not off the top of my head. 5 understand you to say it was -- no. That was Botox. 5 Q Did you ever publish the exposure rate? 6 Just tell me about that trial. It should be in the document, the article 6 7 7 reporting the primary outcomes of the trial. A Yes. This was a randomized trial 8 8 Do you know who the lead author would be comparing women who were undergoing abdominal 9 sacrocolpopexy without preoperative stress 9 on that study where would you expect to see it? incontinence symptoms to determine if the addition 10 A Linda Brubaker. 10 of a Burch colposuspension at the time of the Tell me how you reviewed the MAUDE 11 11 Q abdominal sacrocolpopexy could help prevent stress 12 database at that point in time. 12 A I don't remember a lot of specifics. I 13 incontinence. 13 believe we searched for mesh in the use of prolapse 14 Q And what was the outcome of that study? 14 15 What were your conclusions? 15 surgery. A The Burch was helpful not in 100 -- it did You don't remember actually doing a search 16 16 Q not 100 percent prevent the development of stress relating to, for example, one particular 17 17 18 incontinence after abdominal sacrocolpopexy, but it 18 manufacturer reporting rates, you just looked at the entire database and did that search? 19 was helpful. 19 20 Q And you indicated that in that context you 20 Α Correct. 21 were required to review the FDA MAUDE database? 21 Q Do you remember what your findings were? 22 22 Α 23 Q Tell me about that. 23 Q Did you speak with anyone at the FDA about 24 We were -- the patients at the 24 this? investigative sites were experiencing some mesh 25 25 No. Α

1 Q Have you ever been employed by the FDA? 2 A No. 3 Q Have you ever been a consultant to the 4 FDA? 5 A No, no. 6 Q Have you ever served on any of the FDA 7 advisory committees? 8 A No. 9 Q Have you ever testified at any FDA 9 davisory committees? 10 Q Have you ever testified before any other 11 A No. 12 Q Have you ever testified before any other 13 government institution, any type of hearing? 14 A No. 15 Q Before being retained in this litigation, 16 had you ever had any discussion with any of the 17 employees at Ethicon about their mesh? 18 A No. 19 Q Had you ever had any discussions with any 20 of the employees at Ethicon about transvaginal tape? 11 A No. 12 Q Do you know Piet Hinoul? 12 Q Do you know Piet Hinoul? 13 A No. 14 Q Do you know David Robinson? 15 A I may have met him at one point in the 16 Page 39 1 past. I don't remember clearly. 2 Q Do you know Axel Arnaud? 3 A No. 4 Q Do you know Axel Arnaud? 5 A No. 6 Q Do you know Axel Arnaud? 7 Q Do you know Axel Arnaud? 8 group? 9 A No. 10 Q Just so I'm clear, you don't know 11 Dr. Cosson or Dr. Jacquetin or Dr. Debodinance or any of the people that were involved in the clinical studies on Prolift®? 14 A Correct. 15 Q I take it if you don't know them, you've never spoken with any of them about their studies of repairs? 16 A No. 17 Q Do you know Axel Arnaud? 18 A No. 19 Q Do you know davel Arnaud? 20 Do you know Axel Arnaud? 3 A No. 3 A No. 4 Q Do you know davel Arnaud? 5 A No. 6 Do you know any of the members of the TVM group in France? 7 A To which studies are you referring? 8 Page 39 1 past. I don't remember clearly. 2 Q Do you know of that was involved in the clinical studies on Prolift®? 2 No. 3 A No. 4 Q Do you know of that were involved in the clinical studies on Prolift®? 7 A To which studies are you referring? 8 You can answer. 8 Page 39 1 past. I don't remember clearly. 9 Q Do you know Avel Arnaud? 10 Q Do you know Avel Arnaud? 11 Dr. Cosson or Dr. Jacquetin or Dr. Debodinance or any of the people that were involved in the clinical studies on ot				
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19 Q Do you know Vincent Lucente? 19 Dr. Iglesia about studies involving or her study		·		
170 B 163	20	A Yes.	20	involving Prolift®?
21 Q How do you know Dr. Lucente? 21 A No.				-
22 A By attending the same meetings. 22 Q Have you had any discussion with Dr. Hale		-		
Q Those would be the urogynecology national 23 with respect to the study involving Gynemesh® PS?		, ,		
5, 5,				
5,1	14	meetings professional organizations?	24	A No
125	25	meetings, professional organizations? A Yes.	24 25	A No. Q Do you know any of the physicians who have

			Dags 44
1	Page 42 been involved in the studies of either Prolift+M® or	1	Page 44 A I don't know.
2	Prosima®?	2	Q You did not?
3	A Again, off the top of my head, the only	3	A I did not, no.
4	one I know who was involved in Prosima® was Halina	4	Is this a good time for a break?
5	Zyczynski.	5	MS. JONES: Sure.
6	Q And have you spoken to Dr. Zyczynski about	6	MR. SLATER: Sure. Take a break
7	that?	7	whenever you need.
8	A No.	8	THE WITNESS: Good.
9	Q Was she at Pittsburgh when you were there?	9	(Short recess.)
10	A Yes.	10	BY MS. JONES:
11	Q Have you had any discussion with her about	11	Q Doctor, have you ever discussed the use of
12	the use of mesh in pelvic floor repairs in general?	12	transvaginal mesh for use in pelvic floor surgery
13	A We may have discussed that when we were on	13	with anyone at the FDA?
14	the faculty together. I don't remember	14	A No.
15	specifically.	15	Q Have you ever submitted anything about
16	Q When you were on the faculty there, was	16	your opinions on the use of transvaginal mesh for
17	mesh used in pelvic floor repairs?	17	pelvic floor prolapse to anyone at the FDA?
18	A I don't believe so. If you're can I	18	A No.
19	clarify? Are you talking about stress incontinence	19	Q Other than the reports that you have
20	or prolapse?	20	submitted in this lawsuit, have you ever prepared
21	Q Well, let's separate it. Was it used in	21	any other report or writing on the use of mesh in
22	the context of stress incontinence?	22	pelvic surgery that's not identified in your CV?
23	A Other surgeons, yes.	23	A No.
24	Q You did not use it?	24	(Exhibit No. 1218 was marked for
25	A Correct.	25	identification.)
	Page 43		Page 45
1	Q But other surgeons used, for example, the	1	BY MS. JONES:
2	Q But other surgeons used, for example, the TVT® products?	2	BY MS. JONES: Q Let me show you what's been marked as
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Page 46
                                                                                                               Page 48
    the requests for production from each of the experts
1
                                                            1
                                                                       Yes.
2
    had come out. So I didn't, frankly, even give the
                                                            2
                                                                       For information about products?
    notice to my expert because obviously it's beyond
                                                            3
3
                                                                       Yes.
4
    her expertise to decide what to produce. So those
                                                            4
                                                                   O Anything else that you looked at the FDA
5
                                                            5
    were decisions of counsel.
                                                                website about?
6
              MS. JONES: I understand.
                                                            6
                                                                   A I looked at the advisory panel meeting
7
    BY MS. JONES:
                                                            7
                                                                that they held in September of last year -- last
8
                                                            8
       Q What I want to do is to talk about this
                                                                year, yes.
9
    notice a little bit, Doctor, and talk with you about
                                                            9
                                                                   Q Other than looking at the FDA website for
    what we've asked for and what you have reviewed. I
10
                                                           10
                                                                that type of material, did you look at or did you do
11
    received on Friday, I think, it may have been
                                                           11
                                                                any other independent research?
    Saturday, a supplemental list of materials that you
12
                                                           12
                                                                   A Another example would be looking on the
    have reviewed that I think -- and I'm directing this
                                                                Ethicon website to see what they had available on
13
                                                           13
14 as much to counsel as to you -- I think represents
                                                                their products, what was listed as their current
                                                           14
15 the universe of materials that you have reviewed as
                                                                instructions for use, current material directed at
                                                           15
   of that date, and then I got a note that you've
                                                                patients, things like that.
16
                                                           16
    since looked at Dr. Lucente's deposition.
                                                                   O Okay. What else?
17
                                                           17
18
              MR. SLATER: Right. What we've done,
                                                           18
                                                                   A I would often look at the medical
19 for the benefit of counsel, is -- obviously there's
                                                                literature when an area came up that I didn't feel I
                                                           19
20 a tremendous amount of documents referenced, many
                                                                had enough background on, find relevant articles,
                                                           20
21 notes and in the context of the reports that have
                                                           21
                                                                and then they would be produced for me.
    been served. Dr. Weber's also endeavored to make a
22
                                                           22
                                                                   Q So you would do, for example, a Medline
23
    list of what she reviewed. So the entire universe
                                                           23
                                                                search for articles on a certain topic and then ask
    would be anything referenced in the reports,
24
                                                           24
                                                                plaintiffs' counsel to send you the actual articles?
25 anything listed in the materials reviewed list. And
                                                           25
                                                                   A Yes.
                                                   Page 47
                                                                                                               Page 49
    I've told my associates now since we're here I want
                                                            1
                                                                   Q And can you tell me what those topics were
1
2
    them to sweep and make sure they haven't missed
                                                            2
                                                               that you asked for articles on?
    anything. And, if necessary, I'll give you today
                                                            3
                                                                   A Those are listed in the materials
3
                                                                reviewed, the articles themselves.
    again if there's anything else to be added so you'll
4
                                                            4
5
    have everything. I think you have it all, but if
                                                            5
                                                                   Q But what I'm asking you is you said that
    you don't, if there's a few stragglers, I'm going to
                                                            6
                                                               there were areas that you did not feel as
6
                                                            7
                                                                knowledgeable about and did research on. I'm asking
7
    make sure you have them.
                                                            8
8
    BY MS. JONES:
                                                                you to tell me what those areas are.
                                                                          MR. SLATER: Objection to the form.
9
        Q Did you review anything, Doctor, other
                                                            9
    than what was sent to you by plaintiffs' counsel?
                                                           10
                                                                          You can answer.
10
                                                                          THE WITNESS: Hernia repair,
        A Yes.
11
                                                           11
                                                               complications and effectiveness of stress
                                                           12
12
           Tell me what that was.
                                                               incontinence products. That's what I can think of
13
        A It's on the list. It would include things
                                                           13
14
    that I found on the FDA home page, for example, the
                                                           14
                                                               off the top of my head.
15
    summary statements for products.
                                                           15
                                                               BY MS. JONES:
        Q Can you just describe for me what
                                                                   Q Have you spoken with any of the plaintiffs
16
                                                           16
    independent research you did other than review the
17
                                                           17
                                                               in this litigation?
18
    materials that plaintiffs' counsel sent to you?
                                                           18
                                                                   Α
                                                                       No.
                                                           19
                                                                       You have reviewed the medical records of
19
        A Well, for example, if I came across a
20
    reference to a product that I wasn't familiar with
                                                           20
                                                               Ms. Gross and Ms. Wicker; correct?
    or didn't already have documentation on, I would
                                                           21
21
                                                                   Α
                                                                       Yes.
22
    look to the FDA database to obtain the summary
                                                           22
                                                                   0
                                                                       Have you reviewed the medical records of
    statement, which contains the indications and so on.
                                                           23
                                                               any other plaintiff?
23
24
        Q When you say you would look at the FDA
                                                           24
                                                                   Α
                                                                       Yes.
25
    database, you would look at the FDA website?
                                                           25
                                                                       How many?
                                                                   Q
```

	Page 50		Page 52
1	A Approximately 10 to 15.	1	A We were specifically discussing the
2	Q Have you prepared reports on any of those	2	urologic aspects from Dr. Elliott's standpoint and
3	women other than Ms. Gross and Ms. Wicker?	3	the urogynecologic aspects from my standpoint.
4	A Yes.	4	Q Was that related to a specific plaintiff
5	Q Can you tell me the names of those women?	5	or just in general?
6	A Donna Rogers and Patricia Firman,	6	A Both.
7	F-I-R-M-A-N.	7	Q Well, what I'd like you to do is tell me
8	Q Anyone else?	8	everything you can remember about that conversation.
9	A No.	9	A We were discussing the urinary retention
			· · · · · · · · · · · · · · · · · · ·
10	Q Had you spoken with the treating	10	issue, and we discussed the contraindication that
11	physicians or surgeons of any of the plaintiffs in	11	now exists for patients with preexisting pain
12	this litigation?	12	conditions.
13	A No.	13	Q Was anyone on the telephone besides you
14	Q And I assume you've not spoken with any of	14	and Dr. Elliott?
15	their family members, husbands or significant others	15	A Mr. Slater.
16	or anything of that nature?	16	MR. SLATER: I was teaching them.
17	A Correct.	17	BY MS. JONES:
18	Q Other than Mr. Slater, what lawyers have	18	Q How long did that phone call last?
19	you met with in the context of this litigation?	19	A I was on the phone call for approximately
20	A No one else.	20	half an hour.
21	Q In fairness, I know you said that you were	21	Q And when you said that you were discussing
22	contacted and talked with somebody else in	22	contraindications of pain syndrome, tell me what you
23	Mr. Slater's office, but you've not talked with	23	remember about that discussion.
24	anyone that's not associated with Mr. Slater's	24	A The knowledge that has been gained since
25	office here; is that correct?	25	the Prolift® product and procedure was marketed that
	office fiere, is that correct.	3	the Frontes product and procedure was marketed that
	Page 51		Page 53
1	Page 51 A Correct.	1	Page 53 women who have a preexisting pain condition are
1 2	A Correct.	1 2	women who have a preexisting pain condition are
2	A Correct. Q Have you attended any meetings in which	2	women who have a preexisting pain condition are relatively or absolutely contraindicated from
2	A Correct. Q Have you attended any meetings in which other expert witnesses were present?	2 3	women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure.
2 3 4	A Correct. Q Have you attended any meetings in which other expert witnesses were present? A No.	2 3 4	women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure. Q And when you say that, it's based upon
2 3 4 5	A Correct. Q Have you attended any meetings in which other expert witnesses were present? A No. Q Have you participated in any phone calls	2 3 4 5	women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure. Q And when you say that, it's based upon what?
2 3 4 5 6	A Correct. Q Have you attended any meetings in which other expert witnesses were present? A No. Q Have you participated in any phone calls with other expert witnesses for the plaintiffs?	2 3 4 5 6	women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure. Q And when you say that, it's based upon what? A Upon their higher risk of exacerbation of
2 3 4 5 6 7	A Correct. Q Have you attended any meetings in which other expert witnesses were present? A No. Q Have you participated in any phone calls with other expert witnesses for the plaintiffs? A Yes.	2 3 4 5 6 7	women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure. Q And when you say that, it's based upon what? A Upon their higher risk of exacerbation of their existing pain condition or the development of
2 3 4 5 6 7 8	A Correct. Q Have you attended any meetings in which other expert witnesses were present? A No. Q Have you participated in any phone calls with other expert witnesses for the plaintiffs? A Yes. Q And was that on more than one occasion?	2 3 4 5 6 7 8	women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure. Q And when you say that, it's based upon what? A Upon their higher risk of exacerbation of their existing pain condition or the development of a new pain condition.
2 3 4 5 6 7 8	A Correct. Q Have you attended any meetings in which other expert witnesses were present? A No. Q Have you participated in any phone calls with other expert witnesses for the plaintiffs? A Yes. Q And was that on more than one occasion? A No.	2 3 4 5 6 7 8 9	women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure. Q And when you say that, it's based upon what? A Upon their higher risk of exacerbation of their existing pain condition or the development of a new pain condition. Q And were you giving that information to
2 3 4 5 6 7 8 9	A Correct. Q Have you attended any meetings in which other expert witnesses were present? A No. Q Have you participated in any phone calls with other expert witnesses for the plaintiffs? A Yes. Q And was that on more than one occasion? A No. Q With whom did you speak?	2 3 4 5 6 7 8 9 10	women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure. Q And when you say that, it's based upon what? A Upon their higher risk of exacerbation of their existing pain condition or the development of a new pain condition. Q And were you giving that information to Dr. Elliott or vice versa?
2 3 4 5 6 7 8 9 10 11	A Correct. Q Have you attended any meetings in which other expert witnesses were present? A No. Q Have you participated in any phone calls with other expert witnesses for the plaintiffs? A Yes. Q And was that on more than one occasion? A No. Q With whom did you speak? A With Dan Elliott.	2 3 4 5 6 7 8 9 10	women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure. Q And when you say that, it's based upon what? A Upon their higher risk of exacerbation of their existing pain condition or the development of a new pain condition. Q And were you giving that information to Dr. Elliott or vice versa? A We were discussing it.
2 3 4 5 6 7 8 9 10 11 12	A Correct. Q Have you attended any meetings in which other expert witnesses were present? A No. Q Have you participated in any phone calls with other expert witnesses for the plaintiffs? A Yes. Q And was that on more than one occasion? A No. Q With whom did you speak? A With Dan Elliott. Q Have you spoken with any of the other	2 3 4 5 6 7 8 9 10 11 12	women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure. Q And when you say that, it's based upon what? A Upon their higher risk of exacerbation of their existing pain condition or the development of a new pain condition. Q And were you giving that information to Dr. Elliott or vice versa? A We were discussing it. Q Well, can you tell me in what context you
2 3 4 5 6 7 8 9 10 11 12 13	A Correct. Q Have you attended any meetings in which other expert witnesses were present? A No. Q Have you participated in any phone calls with other expert witnesses for the plaintiffs? A Yes. Q And was that on more than one occasion? A No. Q With whom did you speak? A With Dan Elliott. Q Have you spoken with any of the other witnesses	2 3 4 5 6 7 8 9 10 11 12 13	women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure. Q And when you say that, it's based upon what? A Upon their higher risk of exacerbation of their existing pain condition or the development of a new pain condition. Q And were you giving that information to Dr. Elliott or vice versa? A We were discussing it. Q Well, can you tell me in what context you were discussing it? Were you talking about it in
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	A Correct. Q Have you attended any meetings in which other expert witnesses were present? A No. Q Have you participated in any phone calls with other expert witnesses for the plaintiffs? A Yes. Q And was that on more than one occasion? A No. Q With whom did you speak? A With Dan Elliott. Q Have you spoken with any of the other witnesses A No. Q for the plaintiffs?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure. Q And when you say that, it's based upon what? A Upon their higher risk of exacerbation of their existing pain condition or the development of a new pain condition. Q And were you giving that information to Dr. Elliott or vice versa? A We were discussing it. Q Well, can you tell me in what context you were discussing it? Were you talking about it in the context of a specific plaintiff? A Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A Correct. Q Have you attended any meetings in which other expert witnesses were present? A No. Q Have you participated in any phone calls with other expert witnesses for the plaintiffs? A Yes. Q And was that on more than one occasion? A No. Q With whom did you speak? A With Dan Elliott. Q Have you spoken with any of the other witnesses A No. Q for the plaintiffs? A By e-mail.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure. Q And when you say that, it's based upon what? A Upon their higher risk of exacerbation of their existing pain condition or the development of a new pain condition. Q And were you giving that information to Dr. Elliott or vice versa? A We were discussing it. Q Well, can you tell me in what context you were discussing it? Were you talking about it in the context of a specific plaintiff? A Yes. Q And who was that?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A Correct. Q Have you attended any meetings in which other expert witnesses were present? A No. Q Have you participated in any phone calls with other expert witnesses for the plaintiffs? A Yes. Q And was that on more than one occasion? A No. Q With whom did you speak? A With Dan Elliott. Q Have you spoken with any of the other witnesses A No. Q for the plaintiffs? A By e-mail. Q Let's see if I can separate these. When did your conversation with Dan Elliott occur?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure. Q And when you say that, it's based upon what? A Upon their higher risk of exacerbation of their existing pain condition or the development of a new pain condition. Q And were you giving that information to Dr. Elliott or vice versa? A We were discussing it. Q Well, can you tell me in what context you were discussing it? Were you talking about it in the context of a specific plaintiff? A Yes. Q And who was that? A The plaintiffs Linda Gross and Pamela Wicker.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A Correct. Q Have you attended any meetings in which other expert witnesses were present? A No. Q Have you participated in any phone calls with other expert witnesses for the plaintiffs? A Yes. Q And was that on more than one occasion? A No. Q With whom did you speak? A With Dan Elliott. Q Have you spoken with any of the other witnesses A No. Q for the plaintiffs? A By e-mail. Q Let's see if I can separate these. When did your conversation with Dan Elliott occur?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure. Q And when you say that, it's based upon what? A Upon their higher risk of exacerbation of their existing pain condition or the development of a new pain condition. Q And were you giving that information to Dr. Elliott or vice versa? A We were discussing it. Q Well, can you tell me in what context you were discussing it? Were you talking about it in the context of a specific plaintiff? A Yes. Q And who was that? A The plaintiffs Linda Gross and Pamela Wicker.
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Page 54

BY MS. JONES:

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Q I'm entitled to ask you.

A You're entitled to ask me. All right. All right. His opinions, as I recall, were that the urinary retention that Linda Gross experienced was a direct result of the Prolift® procedure. And the fact that Pamela Wicker had preexisting pain conditions in her interstitial cystitis and her migraine headaches is a contraindication to her having undergone the Prolift® procedure, which is known now.

- Q Did Dr. Elliott express an opinion to you as to whether or not at the time that Ms. Wicker received her Prolift® that information was known?
- A That information was foreseeable by Ethicon. They did not warn physicians and patients of that likelihood.
- Q My question was a little bit different. It was whether or not it was known. Had it been published in the medical literature?
- A It was not at the time that the plaintiffs underwent their surgery.
- Q Now, you said that those were the opinions that Dr. Elliott expressed to you. What opinions did you share with him, if any?

Page 56 1

tell me what the difference is in terms of the way

- 2 you approached it from the way he approached it. What facts, what knowledge, whatever that you had 3
- 4 from the urogynecological spectrum did you use to

5 educate him, if so, and vice versa? 6

MR. SLATER: Objection. The foundation of the question assumes aspects -- it's just not accurate foundation.

You can answer as best you can and tell her what went on during the conversation.

THE WITNESS: I can answer from my perspective as a urogynecologist. I cared for women exclusively. My training has been in the care of women exclusively. My experience may be broader in the care of women with prolapse -- I don't know that for a fact -- regarding Dr. Elliott's practice. So my experience, my training and experience, in caring specifically for women with pelvic floor disorders gives me the background to interpret the clinical events and that's the basis for my opinions. BY MS. JONES:

O Did Dr. Elliott share with you any insights that you had not previously had?

24 No. I'd like to expand on that a little. 25 I think he has a greater experience in caring for

Page 55

I agreed with his opinions.

O My recollection is that you said, Doctor, that you were discussing with him and you shared with him information, facts, opinions, whatever, from the urogynecological standpoint and he was, as I recall what you said, expressing opinions to you from the urological standpoint; am I right?

A Yes.

Q How did those differ in terms of -- what information were you sharing with him from the urogynecological standpoint?

The two different specialties have a lot of overlap. They also have their different perspectives. And I think by discussing our perspectives and our opinions that, for example, urinary retention in Linda Gross was caused by the Prolift® product and procedure, that he professed that opinion on the basis of his urologic training and experience and I professed that opinion on the basis of my urogynecologic training and experience.

- Q Did the two of you reach those opinions by approaching the subject from different viewpoints?
- A From the perspective of our differing specialties, yes.
 - Q What I'd like for you to do then is to

Page 57 women and men perhaps with interstitial cystitis and

2 that that may give him greater insight into the 3

complications that Pamela Wicker has experienced and also into the possible diagnosis that Dr. Benson 4 5 attributed to findings at the time of a cystoscopy

with Linda Gross after her Prolift® surgery.

- O Other than Dr. Elliott, have you spoken with any of the other expert witnesses identified by the plaintiffs in this case?
- Α
- 11 When you reviewed Ethicon documents or the 12 literature in this case, did you take any notes?
 - Α Yes.
 - Q And where are those notes?
- 15 Α On my computer and handwritten.
 - Q But you did not bring those with you?
- 17 Α No.
- Q Did you separately mark in any way on the 19 documents?

Let me ask this first: Did you receive those documents electronically or in hard copy?

Both.

22 23 MR. SLATER: I just want to place an objection. I'm generally not somebody who 24 25 overobjects during a deposition and I don't mind

making a record, but to the extent that and I think it was essentially exclusively what J Dr. Weber was doing was part of her interaction with 4 me and part of our work product, I'm not necessarily going to agree to produce these things. I don't mind you setting a record because I know you want to find out what exist, but a lot of this may come within the work product privilege. MS. JONES: Okay. I don't think her notes come within the work product privilege and how she maintained them and did that. She maintained them and that we're not entitled to drafts and all, but my she maintained them and that we're not entitled to drafts and all, but my she maintained them and that we're not entitled to drafts and all, but my she maintained them and that we're not entitled to drafts and all, but my she maintained them and that we're not entitled to drafts and all, but my she maintained them and that we're not entitled to drafts and all, but my she maintained them and that we're not entitled to drafts and all, but my she maintained them and that we're not entitled to drafts and all, but my she maintained them and that we're not entitled to drafts				
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	Page 62		Page 64
1	been billed at \$350 an hour?	1	specifically sat down and said I'm going to start
2	A Earlier in our working relationship it was	2	drafting my report?
3	\$250 an hour.	3	A I don't remember.
4	Q Can you tell me approximately when you	4	Q Did you submit statements to counsel for
5	changed the rate from 250 to 350?	5	your time?
6	A Perhaps the spring of this year. O 2012?	6 7	A Yes.
7 8	Q 2012? A I believe so.	8	Q When you would submit those statements to counsel for your time, would you itemize what you
9		9	had done?
10	Q How much have you been compensated at this point?	10	A I have done that recently. I hadn't done
11	A I don't know.	11	that for the entire course of
12	Q You didn't bring your financial statements	12	Q When you say you would itemize what you
13	with you?	13	had done, give me an example of how you would
14	A I understood from Adam that that had been	14	itemize it.
15	disclosed.	15	MR. SLATER: I'm going to preserve my
16	MR. SLATER: You have our	16	objection. I'll let her answer the question, but
17	disclosures. They didn't give that to you?	17	I'm not waiving any objections to work product.
18	MS. JONES: I have not seen them.	18	You can answer.
19	MR. SLATER: I'll have somebody print	19	THE WITNESS: I would make a table.
20	a copy. We produced them for all our experts. The	20	The first column has the date, the second column has
21	hours spent, the rates, when the rate went from 250	21	the tasks, and the third column has documents
22	to 350, the whole thing was produced.	22	produced. And what I mean by that is documents that
23	MS. JONES: Okay. I apologize. If I	23	I myself have written that I'm submitting to
24	have	24	Mr. Slater.
25	MR. SLATER: It's no big deal.	25	
I			
	Page 63		Page 65
1	MS. JONES: It's either it never got	1	BY MS. JONES:
2	MS. JONES: It's either it never got to me or I've overlooked it.	2	BY MS. JONES: Q Have you written documents for Mr. Slater
2 3	MS. JONES: It's either it never got to me or I've overlooked it. MR. SLATER: And I told defense	2	BY MS. JONES: Q Have you written documents for Mr. Slater other than drafts of this report?
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	Page 66		Page 68
1	obviously; right?	1	A Rachel Zimmerman.
2	MS. JONES: Yeah.	2	Q Other than Rachel Zimmerman, have you
3	THE WITNESS: No.	3	given other interviews relating to the use of mesh
4	BY MS. JONES:	4	in pelvic surgeries?
5	Q Have you met any of the other plaintiffs'	5	A No.
6	lawyers involved in this litigation?	6	Q Have you ever given any interview on TV or
7	A No.	7	film or anywhere where you've appeared personally?
8	MR. SLATER: In fairness, the guy you	8	A No.
9	met today is a plaintiff lawyer.	9	Q Have you participated in any clinical
10	THE WITNESS: Oh.	10	trials since you left Magee in 2006?
11	MR. SLATER: Jeff Grand is a	11	A I continued to work with NIH until 2008.
12	plaintiff lawyer.	12	Q And you were the program manager there;
13	THE WITNESS: Oh, I beg your pardon.	13	correct?
14	MS. JONES: Just for the record, so	14	A Yes.
15	that the record is clear, the notice of the	15	Q But in terms of actually performing the
16	deposition is marked as Exhibit 1218.	16	surgery or prescribing the Botox, for example, that
17	BY MS. JONES:	17	was done by doctors in the network and not you; am I
18	Q Have you provided any written documents to	18	right?
19	counsel other than drafts of your report and	19	A Yes.
20	invoices?	20	Q Have you written anything, Doctor, about
21	MR. SLATER: My position is the same.	21	mesh that's not shown on your CV, other than
22	That was the question you asked. I'm taking the	22	obviously the reports in this litigation?
23	same position. You're not asking like did she send	23	A Written for publication do you mean?
24	me a medical article or something, you're talking	24	Q Well, written for publication, yes. Have
25	about things that she authored; correct? I mean, I	25	you written anything for publication that's not on
25	about things that she authored, correct: Timean, I	23	you written anything for publication that's not on
	Page 67		Page 60
1	have no problem with you asking did she ever send me	1	Page 69 your CV?
2	an article or something she found, but in terms of		VOULCY:
3		רו	,
	things that she wrote my position is that's work	2	A No.
	things that she wrote, my position is that's work	3	A No. Q Have you written anything that has been
4	product, that's my interaction with my expert. And	3 4	A No. Q Have you written anything that has been submitted to any third party that's not on your CV?
4 5	product, that's my interaction with my expert. And I would accord you the same position as well.	3 4 5	A No. Q Have you written anything that has been submitted to any third party that's not on your CV? A No.
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4 5 6 7 8	product, that's my interaction with my expert. And I would accord you the same position as well. BY MS. JONES: Q Have you sent to Mr. Slater information that you gleaned from any independent research?	3 4 5 6 7 8	A No. Q Have you written anything that has been submitted to any third party that's not on your CV? A No. Q Let me give you an example. You've never written anything to any of the medical schools or training programs with respect to your opinions on
4 5 6 7 8 9	product, that's my interaction with my expert. And I would accord you the same position as well. BY MS. JONES: Q Have you sent to Mr. Slater information that you gleaned from any independent research? A For example, if I came across an article	3 4 5 6 7 8 9	A No. Q Have you written anything that has been submitted to any third party that's not on your CV? A No. Q Let me give you an example. You've never written anything to any of the medical schools or training programs with respect to your opinions on mesh?
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Page 70 Page 72 Q Well, let me just see if I can do this. with me. 1 1 2 Did you ever perform any transvaginal placement of 2 If we look at your professional 3 3 mesh in any surgery? experience, you show on there 2008 till present the 4 4 International Academy of Pelvic Surgery. And we've A Yes. 5 5 Q What types of surgery did you perform already spoken about that. As I recollect and involving transvaginal placement of mesh? 6 understand, your role is to summarize, if you will, 6 7 A TVT®. 7 the current medical literature on urogynecology? 8 8 O And when you used the TVT®, did you use A Let me clarify. I select a topic when -once I've looked at the medical literature and if an 9 Ethicon's TVT®? 9 10 A Yes. 10 article of interest has been recently published, I 11 Q And can you tell me when you began using 11 may select that and then a handful of other articles on that topic. So it's theme-based. And then I Ethicon's TVT®? 12 12 critically review the articles I've selected and 13 A When I was at the Cleveland Clinic. That 13 provide a summary and a clinical take-home message 14 was just beginning to be available. 14 Q My recollection is that TVT® became for the audience. 15 15 available in 1998. Would you have been using it Q Do you do that once a month? 16 16 Once a month. about that time? 17 17 Α 18 A No, I don't think so. I think it would --18 Q And when you say that you provide the clinical information and take-home article, that my recollection it is closer to the time I left the 19 19 would be written and posted on the website? clinic. And then when I joined Magee-Womens 20 20 Hospital, I did not use TVT®. 21 A Correct. 21 22 Q Had you used anything before you used 22 And are those writings and opinions attributed to you specifically? 23 23 TVT®? 24 A In terms of a mesh product --24 Α 25 25 Q Yes. Q So if we do a search, for example, of the Page 71 Page 73 website, we would be able to find all of the A -- for stress incontinence? No. 1 1 2 2 Q Do you have any recollection of using any comments that you had written over a period of time? sling product other than a TVT® for urinary 3 A Yes. And I would like to add that you 3 won't find anything for the past two or three months 4 incontinence? 4 5 A No. 5 because I have devoted my time to preparing for this 6 6 and the trial. So I haven't done it continuously Q At any time? 7 7 except for the past two or three months. 8 8 (Exhibit No. 1219 was marked for Q When you said you devoted yourself to 9 identification.) 9 preparing for this and the trial, what have you BY MS. JONES: 10 done? 10 Q I'm going to show you, Doctor, what I've 11 A I've continued to review documents. I've 11 read deposition testimony. I have continued to marked as Exhibit 1219, which is a copy of your CV 12 12

Q I'm going to show you, Doctor, what I've marked as Exhibit 1219, which is a copy of your CV that we were provided. I'd like to ask you whether or not this is current.

A Yes, this is current.

- Q Do you have any publications that are in process?
 - A No.

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Q You don't have any that you've submitted, for example, that you're waiting to hear on acceptance?

A Correct.

Q What I want to do is talk with you about your CV a little bit. We covered some of this so I'm going to jump around a little bit. Just bear

A I've continued to review documents. I've read deposition testimony. I have continued to produce the supplemental reports. I've read the reports of the defense and plaintiffs' experts.

Q And I know that we're going to get presumably the disclosure here, but can you tell me on a just daily or weekly basis how much of your time that's taken?

A It varies. Would you like to restrict that to a time frame and perhaps I can answer you more accurately?

Q Well, you said that the last two or three months you had devoted most of your time to working on this case. And I'm just trying to get a sense of whether that's 40 hours a week and you're working,

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Page 74 Page 76 you know, a typical day or it's, you know, three 1 three-quarters time. 2 hours one week and 40 hours the next week. 2 Q Let me see if I can put it in this A I would say over the last couple of months perspective. When you say "three-quarters time," 3 3 4 it's been more steady. Let me think for a minute 4 does that mean that you might be spending as much as 5 5 30 hours a week doing that? and I'll do my best to give you a weekly estimate. I would estimate a range of between 25 to 6 A Correct. 6 7 30 hours a week. 7 And during that same period of time, you 8 8 also have listed BioScience Writers. Were you doing O Other than these review articles, themes 9 the same thing for that group? 9 that you write for the International Academy of Pelvic Surgery, have you written other materials for A Similar. A wider range of documents. 10 10 11 that group? 11 When I was working with The Medical Editor, that was almost exclusively academic manuscripts. The 12 A No. 12 documents with BioScience Writers was a wider range 13 Q You also show that you were a freelance 13 editor for The Medical Editor. What is The Medical 14 of documents. 14 15 Q When you're talking about academic 15 Editor? manuscripts, are you talking about the manuscripts 16 A That is a service run by Carl Richmond, as 16 you can see, who accepts typically manuscripts from 17 that are being written by academicians or are they 17 written for academicians? 18 scientists all other the world who pay for editing 18 services to improve the clarity, the grammar, the 19 Both. Α 19 20 spelling, make it consistent with the journal's 20 0 How do you define academic manuscripts? A manuscript that's intended to be requirements. 21 21 22 published in a peer-reviewed publication. 22 Q And as a freelance editor for that group, I assume that the way it would work is periodically Q And I take it then that the BioScience 23 23 Writers might or might not be headed for peer-review they would send you a paper and you would edit it 24 24 publication but perhaps would be for some popular or 25 and send it back? 25 Page 75 Page 77 A Correct. 1 industry trade publication? 1 2 O In the course of that, was it limited to 2 A Not necessarily, not necessarily for any particular field? publication. Grant applications, things like that. 3 3 Q And, again, it would not be limited to A No. 4 4 5 Q So this is not necessarily 5 urogynecology? urogynecology-related? 6 A Correct. 6 7 7 O In none of these positions after 2007 up A Correct. 8 to date have you been engaged in doing any original 8 Q How many papers approximately have you 9 edited for The Medical Editor? 9 research: is that correct? A Hundreds. 10 A The last publication I have in terms of 10 original research was published last year, in 2011. 11 Q One hundred? 11 So that was something I was involved in leading up 12 12 Α Hundreds. 13 Q Hundreds. I take it that you no longer do 13 to 2011. 14 that? 14 0 Well --15 15 A Can I correct something? Because I Α Correct. How were you compensated for that? Were realize I've been speaking of my time at NIH as if 16 16 it went through 2008, but it really ended at the end you on a salary? I assume as a freelance editor you 17 17 18 were compensated on the basis of each paper? 18 of 2007 before going into 2008. Q Okay. What is the publication that you're 19 19 20 Q So if it took you ten hours to edit, you 20 referring to in 2011? would be paid a certain amount by the hour? A It's on Page 6 of 25, the first one. 21 21 22 A Correct. 22 0 This is the reanalysis of the randomized Q And when you say that you had done trial? 23 23 hundreds, was that essentially a full-time position? 24 24 Α Correct. 25 A Perhaps not full time. Perhaps 25 That randomized trial was actually done Q

Page 78 Page 80 about 2000, wasn't it? floor disorders, how did that come about? I mean, 1 1 2 A Approximately. 2 how did you get involved with that program? 3 Q I'm not sure exactly. My recollection is 3 A In the late 1990s the professional 4 that you published the results of that in 2001; is 4 organizations, the leaders of our professional 5 5 organizations, met with the leaders at NIH to that right? discuss the lack of high-quality research in female 6 A I think that's correct, yes. 6 7 So the trial itself was actually conducted 7 pelvic floor disorders. And with that encouragement 8 in the late '90s, early 2000? 8 NIH created a position in the National Institute of 9 A Correct. 9 Child Health and Human Development to develop a 10 Q And this reanalysis was done after you 10 specific research program devoted to female pelvic 11 were retained as an expert in this litigation? 11 floor disorders. And at one of our professional meetings the director of the NICHD at that time, 12 A Correct. 12 13 Have you published other materials since 13 Duane Alexander, came and spoke to the group and announced that this position was available. So I 14 you were engaged as an expert in this litigation? 14 A In the nonpeer-reviewed literature, yes. applied and I was selected. 15 15 Q Can you identify for me what those Q Were you in the group that went initially 16 16 to discuss this program with the NIH? 17 publications are? 17 18 A Page 13 of 25. These are in reverse 18 19 chronological order so that would be, let's see, I 19 Q Do you know who was? 20 guess just the first two. 20 The only person I can remember is Richard Α Q Do you remember whether or not you had 21 21 Bump. 22 already been contacted by plaintiffs' counsel when 22 Q As I recall, what you said was that the you wrote commercial pressures and professional 23 23 leadership of the professional organization went. 24 ethics revisions to the ACOG practice bulletins? 24 Was that the leadership of ACOG or was it --A No, not ACOG. I believe it was the 25 A I don't remember. 25 Page 79 Page 81 Q You certainly by the time that you had 1 American Urogynecologic Society and the Society of 1 written that had addressed and made comments with 2 2 Gynecologic Surgeons. respect to lawyer advertising with respect to pelvic 3 Q And when you were selected to run that 3 program, what instructions were you given by the NIH mesh surgeries, hadn't you? 4 4 5 A I'm sorry? 5 in terms of what they expected, what was going to be 6 Q By this point in time you certainly were 6 done? 7 7 aware and eventually wrote about lawyer advertising They wanted to develop several initiatives 8 related to the use of mesh in pelvic floor repairs, 8 to solicit investigator -- I'm sorry -- to solicit 9 didn't you? 9 applications from investigators in the field. A I'm not familiar with what you're 10 Because there hadn't been dedicated NIH funding for 10 referring to. Can you show me that? female pelvic floor disorders in the past, 11 11 We might get to it. You don't remember 12 investigators would have a very high level of 12 0 competition to obtain NIH funding. So part of my 13 that? 13 A I said I'm not familiar with what you're job was to develop these initiatives to solicit 14 14 15 15 applications from the investigators in the field to referring to. Q You do remember seeing lawyer advertising let them know that NIH is concerned about the lack 16 16 with respect to mesh being used in pelvic floor of high-quality research in this field and is 17 17 18 repair surgeries, don't you? 18 dedicating research funding to advance the science. And those are called requests for applications. And 19 Α Yes. 19

Q And that you saw that early on after the 2008 public health notice?

A I don't remember specifically.

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Q If we look at the next entry on your CV where you said you were medical officer or the program director for research for female pelvic

So we had an initiative focused on basic science research in female pelvic floor disorders,

the limits of the funding, several are selected for

they're posted with a deadline. And then the

applications come in, are reviewed, and depending on

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funding.

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epidemiological research, and then for clinical research we established the clinical trials network, the pelvic floor disorders network, which also went out as a request for applications specifically for the investigative sites and also for the data coordinating center for investigators to submit applications and be selected for participation.

Q And the way I understand NIH works is you post, for example, a request for application and then an investigator, a doctor, would submit a proposal in which he says I'd like to do a study, basically submits the protocol or grant request, I'd like to do a study involving these issues, these number of patients, and this outcome, and the NIH and then presumably you would look at that proposal and protocol and say this looks like a good study and I'm going to give him the money to conduct it?

- A It's a little --
- Q I know that's simplified.
- 20 A Yes.

- Q But am I essentially correct?
- 22 A The main difference is the review 23 committee is independent of the NIH staff. There 24 are standing committees and then for the RFA 25 specifically we call an ad hoc committee to review

Q And when you noted that you were the clinical monitor, that you would review adverse reports, you obviously were not a blinded investigator here, were you?

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Page 85

A Perhaps I misunderstood the question. With the clinical monitor, who is one person, and the safety monitor, who is another person, from the data coordinating center, we would review the adverse events. And those were blinded. The data were blinded to us as we reviewed the adverse events.

- Q Okay. And was that then a review of all of those and all of the different clinical trials that were being sponsored at the time?
 - A Correct.
- Q When you were doing this and acting as the medical officer program director, how much time did you spend in that capacity?

A That changed over the years. When I began in 1999, it was 25 percent. And then it increased. I believe when I left Cleveland to go to Pittsburgh, it increased to 50 percent. When I stopped my surgery practice, it went to 75 percent. And then when I left Magee-Womens Hospital altogether, it went to a hundred percent.

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the applications, they're scored, and then based on the score is the typical way that funding decisions are made.

- Q All right. So you didn't yourself then personally make those funding decisions?
 - A Correct.
- Q You had an ad hoc committee that would have reviewed all of them and decided which ones would be the most appropriate for funding?
- A Yes. As I said, they would score them and then obviously we would rank them by score. We have input, depending on what we see as the greatest need in the field, but generally the funding decisions go very strongly by score.
- Q And then once a study is funded, you as the program director would monitor that study and receive reports, interim reports, in the context of the study?
 - A Correct.
- Q You note on your CV that you were involved with the investigational new drug trial. Is that the Botox --
- 23 A Correct.
- 24 Q -- trial you referenced earlier?
 - A Yes.

Q And you left the hospital in the end of 2005, so you had a two-year period that it was a hundred percent of the time?

A Close. I believe I left Magee in May of 2006.

- 6 Q I'm sorry. I think you probably said that 7 and I --
 - A Yeah, in the range of a year and a half.
 - Q And when you said that it became a hundred percent of your time, did you spend more and more time there or was it just a hundred percent of the time because you no longer had the obligations at Magee?
 - A The latter.
 - Q So would it be fair to say that the amount of time, not the percentage of time but the amount of time that you spent as program director basically remained the same over the entire period of time?
 - A No, no. It increased.
- Q Okay. But it didn't increase -- this is what I'm trying to say: After you left Magee, it remained the same?
 - A No. It went from 75 percent to 100 percent.
 - Q I know. I think that's where we

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    miscommunicated a minute ago, because I thought you
                                                                stands for. But it is an arrangement between the
                                                            1
2
    told me it went to a hundred percent of your time
                                                            2
                                                                NIH and my institution to account for a certain
    because you were no longer working at Magee but it
                                                                percentage of my time that I'm not spending working
3
                                                            3
4
    didn't mean extra time. Do you see the difference
                                                            4
                                                                for the institution, the Cleveland Clinic at that
5
                                                            5
    that I'm saving?
                                                                time.
6
       A No.
                                                            6
                                                                   Q So the arrangement was really between the
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        Q
           Okay. It's one thing to say I'm spending
                                                            7
                                                                NIH and the Cleveland Clinic for your time?
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    75 of my time on this and 25 percent of my time at
                                                            8
                                                                       Correct.
    Magee, but if that 25 percent of the time at Magee
                                                            9
                                                                       And did the same thing hold true with
                                                                   0
    goes away and you're only working at NIH, then it
                                                               respect to Magee when you moved to Magee?
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                                                           10
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    becomes a hundred percent of the time but it doesn't
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                                                                       Correct.
    necessarily mean more time. And I thought that was
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                                                           12
                                                                       And at that point in time it changed from
    what you told me had happened. And I may have
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                                                           13
                                                                25 percent to 50 percent?
    misunderstood.
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                                                                   Α
                                                                       Correct.
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       A I am not sure what you're asking. I'm
                                                                   Q And at what point in time did it change to
                                                           15
16
    sorry.
                                                           16
                                                               75 percent?
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       Q All right. Let me see if I can do it this
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                                                                   A When I discontinued my surgical practice.
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    way: When you were at Magee and you said you were
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                                                                   Q At the end of 2004?
    spending 75 percent of your time working as the
                                                                       Yes, I believe that was the fall of 2004.
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    program director -- correct?
                                                           20
                                                                   Q You said that you left Magee-Womens
                                                                Hospital in June of 2006?
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       A Yes.
                                                           21
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       0
           -- how much time was that?
                                                           22
                                                                   A I believe it was Mav.
                                                                       And why did you leave the hospital at that
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       A You know, these time calculations are
                                                           23
                                                                   Q
24
    artificial.
                                                           24
                                                                time?
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       Q I understand. I'm just asking for you to
                                                           25
                                                                   A I wanted to be able to devote all my time
                                                   Page 87
    give me an estimate. You know, did you spend 30
                                                            1
1
2
    hours a week on it?
                                                            2
3
               MR. SLATER: If you can reasonably
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    estimate it. If you find it to be a guess, she
                                                            4
5
    doesn't want you to just guess at something.
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6
              THE WITNESS: It would be probably in
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7
    the range of 50 to 60 hours a week.
                                                            7
                                                            8
8
    BY MS. JONES:
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        Q A week? That would have been what you
                                                            9
    were spending in 2005?
                                                           10
                                                                then devote myself to the NIH.
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        A No. In 2006, after I -- no, no. I'm
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sorry. You're correct. You're correct.

13 Q That's what were spending in 2005. What did you spend in 2006? 14 15

A Probably 60 to 80.

Q Bear with me. I know I'm repeating myself. When you started this, you initially were at the Cleveland Clinic; correct?

A Correct.

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Q And at that point in time you were spending about 25 percent of your time there?

A Correct.

Q Did you have a contract with the NIH?

They have a mechanism that's called IPA.

What's that stand for? I don't remember what that 25

to the NIH work. And I can expand on that a little if you like. I came to Magee with the specific idea of developing a new fellowship program in female pelvic medicine and reconstructive surgery, which is a long name that's been given to our subspeciality of urogynecology. And I accomplished that and we graduated several fellows and it was running along very smoothly, so I felt that it was safe to carry on with the faculty that were in place and I could

Q When you went to Magee, at the time that you went there, there was no fellowship program?

A Correct.

Did you actually have to go out and hire or retain, bring in other faculty members for that residency program?

MR. SLATER: Fellowship program? MS. JONES: I mean fellowship

19 program.

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THE WITNESS: Not at that time. As we -- it's a three-year fellowship. So we obtained a fellow, the first fellow, in the first year, so there was one fellow; a second fellow in the second

23 year, so there were two fellows; and a third fellow 24 25

in the third year, so there were three fellows. So

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Page 89

Page 90 Page 92 2004. So then I would expect we received we had the full complement of three fellows. 1 1 certification in 2003. That's Page 5 on the bottom. 2 At that time when we had three 2 fellows, then staff were added to increase the 3 Q Okay. In this fellowship program, 3 4 exposure of the fellows to clinical practice and 4 although you did not use transvaginal implanted mesh 5 5 research, for example, things that were important in in your surgeries, did other surgeons at Magee use their fellowship. 6 transvaginal mesh? 6 7 Q Did you ever have more than one fellow per 7 A To the best of my recollection, at or 8 8 around the time I was leaving that was beginning to year --9 9 A No. happen. 10 Q -- in the fellowship program? 10 Q At or about the time you were leaving in 11 A Oh, I take that back. No. At one time we 11 2006? did have two fellows in one year. It occurred with 12 12 Α Correct. a graduating resident that everyone was --13 13 0 At the time that you were there, were graduating from the residency at Magee-Womens slings being used for urinary incontinence? 14 14 15 Hospital that everyone was very impressed with so we A To what type of sling are you referring? 15 16 decided to keep her as well as the fellow who we had Well, were mesh slings being used? 16 Q already arranged to keep -- or, you know, take on. 17 17 Α 18 Q And even though you were the director of 18 Q Was any mesh used at Pittsburgh other than that fellowship program, I assume other faculty for abdominal sacrocolpopexy? 19 19 20 members and other surgeons were involved in the 20 A Not to my recollection, except as I just training of those fellows as well? said, toward the time I was leaving. 21 21 O And toward the time that you were leaving, 22 A Correct. 22 23 what were the surgeons there beginning to use? Q In other words, you weren't the sole 23 I don't remember. 24 person that was there responsible for ensuring that 24 25 25 they were trained? Q Were the residents trained on how to Page 91 Page 93 A Correct. 1 perform surgeries to correct urinary incontinence? 1 2 2 O In the course of developing this program, The fellows; yes. though, would you be responsible for developing the 3 The fellows. I'm sorry. 3 curriculum, I guess, in terms of what they should be And what surgeries were they trained on? 4 4 5 taught? 5 A Slings. A Yes, in a specific sense. In a general 6 Q What types of slings? 6 7 sense the American Board of Obstetrics and 7 A Rectus fascia slings, cadaveric fascia 8 slings, string slings. 8 Gynecology, which is our certifying organization, 9 provided a general outline of the topics that the 9 Q They were not trained on any mesh fellows should be taught. And then we filled in the 10 10 products? specifics of exactly how they were going to obtain A Not to my recollection. 11 11 12 that knowledge. O And can you tell me what training they 12 received with respect to the other types of pelvic 13 Q And did there come a point in time at 13 which ACOG actually certified that fellowship? organ prolapse surgery? 14 14 15 A The American Board of Obstetrics and 15 A Yes. Abdominal sacrocolpopexy, Gynecology, two different -- yeah, ACOG is the uterosacral ligament fixation and sacrospinous 16 16 ligament fixation for apical prolapse, anterior and professional organization. 17 17 18 Q I apologize. 18 posterior colporrhaphy for anterior and posterior vaginal prolapse, paravaginal repair for anterior 19 A Yes. 19 20 Q And when was that? 20 vaginal prolapse. Let me just glance at my CV and see when 21 21 And were there any procedures in place to evaluate the competencies of the fellows in we graduated the first fellow, because she came 22 22 under the certification. It's a process, as I'm performing each of those surgeries? 23 23 24 sure you can understand. 24 Α Yes.

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Q

Tell me how you do that.

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Okay. So our first fellow graduated in

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A When the fellows were on surgical rotations, each faculty member on a monthly basis -- they rotated on a monthly basis. So at the end of each month's rotation the faculty would provide to me, as the fellowship director, an evaluation of the fellows' progress in learning how to perform the surgeries.
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As the fellows progressed through their fellowship and we saw them evolve in their level of skill and experience, we then arranged the surgeries in such a way that the faculty member was the second assistant, the fellow was the first assistant, and the resident, the senior resident, was the primary operating surgeon. And in that way the fellows would also learn how to teach.

- Q Your fellowship program was, you've already said, certified under the American Board of Obstetrics and Gynecology; correct?
 - A Correct.

- Q Is it a fair statement that the fellows in your program were doctors who had completed training as OB-GYNs?
- A That wasn't a requirement. They could also have graduated from training in urology. Typically they are residents who applied for a

1 A Yes.

Q Regardless of the form, whether it's colporrhaphy or sacrocolpopexy, it can be difficult surgery --

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Page 97

A It can be.

Q -- for a doctor?

It is the type of surgery that generally is best performed in the hands of a specialist; is that fair?

MR. SLATER: Objection.

You can answer.

THE WITNESS: I wouldn't want to make an across-the-board statement agreeing with that. I think in terms of a general philosophy I would agree with that. And certainly the American Board of Obstetrics and Gynecology agreed with that since they created the subspeciality of female pelvic medicine and reconstructive surgery. BY MS. JONES:

Q And it is the specialists, whether they come from a gynecological background or a urological background, that generally perform that surgery?

A I don't know if I can say that on a nationwide basis.

And I would like to correct one thing now

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program, had graduated -- or were going to graduate from residencies in obstetrics and gynecology.

- Q Did residents in OB-GYN at Pittsburgh do pelvic floor repair surgeries?
 - A Yes; under the supervision of the faculty.
- Q So as residents they were taught, for example, to do abdominal sacrocolpopexy?
- A Yes, in -- it depends on the difficulty of the case. The attending physician would make a decision as to whether that was a fellow case or a resident case or both.
- Q But is that one of the surgeries that you would have expected a resident to be trained on during the course of a residency in obstetrics and gynecology?
- A Again, it depends. Some residents have already decided on their future career path. They may decide to go into maternal-fetal medicine or reproductive endocrinology and infertility. And in that situation it is not a good use of surgical teaching to teach those residents how to perform that surgery. That's not going to be part of their clinical practice when they graduate.
- Q Pelvic floor repair surgery is fairly complex surgery, is it not?

that you mentioned urology, because this fellowship was actually jointly boarded, if you will, by the

was actually jointly boarded, if you will, by theAmerican Board of Obstetrics and Gynecology and the

4 American Board of Urology. What would typically

happen in a case like ours as a urogynecologist, the
 American Board of Obstetrics and Gynecology would
 certify my program and the American Board of Urology

would certify programs that were led by urologists.

- Q At the time that you were organizing this fellowship in Pittsburgh, how many fellowship programs were there in the United States?
 - A I believe there were 17.
- Q And that's 17 programs for urogynecology in general, whether it's the American Board of Obstetrics and Gynecology and the American Board of Urology?
 - A I believe that's correct.
- Q So if there were 17 programs, for example, you would generally be training someplace between 50 and 60 fellows a year in this surgery?
- A Collectively. Of course, they only graduate one at a time.
- 23 Q Right.
- A Yes. But at any given moment there may be something like 50 in training at some level between

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the first and the third year. 1

- Q It's a fairly small group of folks that are trained on an annual basis?
 - A It's growing. It's new. But, yes, it is small.
- Q Do you know how many fellowship programs there are today?
 - A I don't.

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- At the time that you were at Magee, from 0 2001 to 2004, you were spending about 50 percent of your time as the program director for the female pelvic floor disorders; correct?
 - A Yes.
- 0 And then 50 percent of your time would have been spent as the program director for the fellowship program?
- A In addition to my clinical practice and my clinical research, yes.
- Q And that's what I want to get to. Can you tell me how your time was broken down during that time period?
- A Well, I had one day in surgery. I think I had one and a half days in the office. And that would leave, say, a half a day roughly for my responsibilities as the program director of the

sacrocolpopexy tends to address those things. 1

2 Working vaginally doing a colporrhaphy, it would be unlikely to address all of the patient's problems so 3 4 it would be a combination of procedures.

Page 100

Page 101

- O Is abdominal sacrocolpopexy the only abdominal surgery you performed?
 - A Well, for prolapse, yes.
 - O Did you perform it for other conditions?
- A Retropubic colposuspension, Burch colposuspension for incontinence.
 - O Anything else?
- No. Oh, excuse me. Paravaginal repair can also be performed usually in conjunction with a Burch.
- Q And do you have any idea during that period of time how many Burch procedures you performed?
- 18 A Well, at Magee I was more likely to perform a sling. That was the experience of the 19 20 faculty group. I should add that at that time we 21 were participating in a clinical trial that was run 22 through the urinary incontinence treatment network. which was also an NIH-funded network that I worked 23 24 with. I didn't lead that one, but I worked with 25 them. That was funded by the National Institute of

Page 99

- fellowship.
- O When you say you had a day and a half in the office, was that a day and a half of clinical care in the office?
 - A Yes.
- Q And can you tell me at that point was your practice here restricted to urogynecology?
- Q And were those patients that were referred to the institution with pelvic floor disorders or urinary incontinence or other issues?
- A They could be referred by other doctors. They could refer themselves in, self-referrals.
- Q And we talked a little bit about your surgical practice, but there you would have had one day of surgery a week from 2001 to 2004?
 - A Correct.
- And during that time do you have any idea, Q Doctor, how many abdominal sacrocolpopexies you performed?
- 21 A That would be relatively uncommon. Maybe, 22 if I'm guessing six per year, three years, 15 to 20.
 - Q And how many colporrhaphies?
- Well, again, unusual to come across a patient who needed a single -- see, abdominal 25

- Diabetes, Digestive Diseases, and Kidney, which is 2 where urologic research funding comes from. And so we, "we" meaning the faculty in the urology and 3 urogynecology divisions, were participating in a 4
- clinical trial comparing Burch and sling procedures 6 for stress incontinence. O And the slings that you were using were
 - the cadaveric, the --
 - A Rectus fascia and what are called string slings, if you're familiar with that terminology.
 - Q And the string slings are what?
 - A I'm basically using sutures anchored in periurethral tissue.
 - Q Going back to my question trying to get an idea, I mean, granted that when you're talking about the vaginal surgeries and the colporrhaphy, for example, any of the other surgeries that you were doing, whether it's the colporrhaphy, the
- sacrospinal ligament fixation, all of those would 19 20 involve vaginal surgery; correct?
- 21
 - A Correct.
- 22 O And all of those would have involved a section of the vagina? 23
- 24 A Correct.
 - And I assume that you would say that as Q

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                                                                                                              Page 104
    with colporrhaphy, any of the vaginal surgeries,
                                                                protocols that you used in the fellowship?
                                                            1
2
    whether it be the sacrospinal ligament fixation or
                                                            2
                                                                    A I mean, there are several textbooks that
    others, would be more likely to be a combination
                                                            3
                                                                we used. Do you want me to try to list them?
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4
    procedure than a stand-alone, separate procedure?
                                                            4
                                                                    O Well, can you tell me what some of the
5
                                                            5
                                                                textbooks were that were used with respect to the
6
           Recognizing that, can you give me an
                                                            6
                                                                prolapse surgery?
7
    approximation of, for example, the number of
                                                            7
                                                                    A Well, for example, Mark Walters and Mickey
8
    colporrhaphies that you performed, whether or not
                                                            8
                                                                Karram have a textbook on Urogynecologic and
9
    they were performed in conjunction with another
                                                            9
                                                                Reconstructive Surgery I believe is the title.
10
    surgery?
                                                            10
                                                                    O And were there others similar to that that
11
       A I would estimate something in the
                                                           11
                                                                were used or recommended in the course of the
    neighborhood of 200 to 300 cases.
12
                                                           12
                                                                fellowship?
        O During the entire time that you were
13
                                                           13
                                                                    A There are some very classic gynecology
                                                                textbooks like TeLinde's, atlases like Clifford
14
    there?
                                                           14
15
       A At Magee-Womens Hospital.
                                                                Wheeless'. I have a textbook in office
                                                           15
        Q At Magee. And the same question with
                                                                urogynecology. That's all I can think of at the
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                                                           16
    respect to the sacrospinal ligament fixation.
                                                                moment. I'm sure there are many more.
17
                                                           17
       A Well, my preference was to perform the
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                                                           18
                                                                    Q I really was just trying to get a feel for
    uterosacral ligament fixation, unless there was a
                                                                the ones that you recollect might have been used or
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                                                           19
    special reason not to do that. So the sacrospinous
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                                                           20
                                                                referred to in the course of that fellowship program
21
    ligament fixation would be less common for me to
                                                           21
                                                                there.
22
    perform.
                                                           22
                                                                    Α
                                                                       Uh-huh.
        Q Divide the two, the uterine ligament
23
                                                           23
                                                                    0
                                                                        So that represents the universe that you
24
    fixation versus the sacral, and tell me
                                                           24
                                                                can remember at this moment; is that correct?
    approximately how many of each you would have done.
25
                                                           25
                                                                    A Correct.
                                                  Page 103
                                                                                                              Page 105
        A I would say probably 80 percent for the
                                                            1
                                                                       Can we have another break?
1
2
    uterosacral ligament suspension and 20 percent for
                                                            2
                                                                           MR. SLATER: Sure.
    the sacrospinous ligament fixation.
3
                                                            3
                                                                           (Discussion off the record.)
                                                                           (Luncheon recess taken from 12:41
        Q And that 80 percent, what number would
4
                                                            4
5
    that be roughly equivalent to?
                                                            5
                                                                p.m. to 1:52 p.m.)
6
        A Yeah, that's really difficult to answer.
                                                            6
                                                                BY MS. JONES:
7
    I could give you a guess as to the total number of
                                                            7
                                                                    Q Doctor, let me follow up with a couple of
    surgeries. But as to the breakdown as to whether
                                                                questions about some of your testimony this morning.
8
                                                            8
9
    they needed an apical prolapse repair with an
                                                            9
                                                                You testified that most of the time when you did
    anterior and posterior -- and/or posterior vaginal
                                                           10
                                                                pelvic floor repair surgery that you used a
10
                                                                combination of different techniques.
11
    repair...
                                                           11
                                                                          MR. SLATER: Objection.
12
           Give me an approximation of the total.
                                                           12
        Q
13
        A I think I did. Did I say 200 to 300?
                                                           13
                                                                          You can answer.
        Q Right. But I understood that was just
                                                                          THE WITNESS: No, I don't recall
14
                                                           14
15
    colporrhaphy. You're suggesting that that's the --
                                                           15
                                                                saying that. I used a combination of different
        A Oh, oh. Yes, yes.
                                                                procedures.
16
                                                           16
            That's the total?
                                                                BY MS. JONES:
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                                                           17
18
           I meant that to be the total.
                                                           18
                                                                    Q Fair enough. So that you would, for
        Α
        Q I'm sorry. I wasn't following. So that
                                                                example, use colporrhaphy together with utero
19
                                                           19
    would basically include over that roughly three-year
                                                           20
                                                                ligament suspension fixation, for example, or some
20
    period at Magee you would have done 2 to 3 hundred
                                                           21
                                                                other procedure?
21
22
    surgeries total?
                                                           22
                                                                   A Uterosacral ligament suspension, yes, for
                                                           23
                                                                apical prolapse if that was the patient's problem.
23
        Α
           For prolapse, correct.
24
            Okay. And while you were there at Magee,
                                                           24
                                                                    Q Why is it that you so often used a
25
    were there any special textbooks or teaching
                                                           25
                                                                combination of two procedures?
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	Page 106		Page 108
1	A It's the nature of the condition of	1	A I would prefer not to guess.
2	prolapse.	2	Q Fair to say you don't remember whether it
3	Q Explain that to me.	3	was macroporous as opposed to microporous?
4	A As surgeons we artificially segment the	4	A Again, I would prefer not to guess.
5	vagina into the apex, the anterior vagina, and the	5	Q And I assume that you don't know whether
6	posterior vagina. In reality the vagina is a	6	it was polypropylene versus Gore-Tex® versus
7	continuous tube. And when prolapse occurs, it's	7	Mersilene® or some other type of mesh?
8	more likely to occur in more than one of the	8	A I would not have used Gore-Tex®. I am
9	segments that we artificially designate than a	9	doubtful I would have used Mersilene®.
10	single segment.	10	Q I think you told us that it was not
11	Q And because it occurs in more than one of	11	partially absorbable?
12	those segments, it's necessary to do for optimal	12	A Correct. No, I didn't tell you that.
13	repair more than one procedure?	13	That was in the context of the CARE trial.
14	A Correct.	14	Q Okay.
15	Q And in addition to those procedures, you	15	A That was part of the study design.
16	would often also do a procedure for urinary	16	Q Do you know whether or not you have used a
17	incontinence at the same time, would you not?	17	partially absorbable mesh?
18	A For stress incontinence.	18	A No, I did not.
19	Q Stress incontinence.	19	Q But you don't know whether or not it was
20	A Again, if that was the woman's problem,	20	polypropylene?
21	yes.	21	A I cannot say that with certainty.
22	Q Understood. But stress incontinence often	22	Q When you were performing a surgery using
23	happens in conjunction with prolapse, does it not?	23	this mesh, did the mesh come, as you can recall, in
24	A Correct.	24	a box, a separate piece of mesh?
25	Q And when you would do an abdominal	25	A A flat rectangular piece of mesh, yes.
	Page 107		Page 109
1	sacrocolpopexy, would you also do or use a	1	Q And were there any instructions or
2	sacrocolpopexy, would you also do or use a combination of procedures?	2	Q And were there any instructions or anything else in the box that you remember looking
2	sacrocolpopexy, would you also do or use a combination of procedures? A As necessary, yes.	2	Q And were there any instructions or anything else in the box that you remember looking at?
2 3 4	sacrocolpopexy, would you also do or use a combination of procedures? A As necessary, yes. Q So that, for example, even though you're	2 3 4	Q And were there any instructions or anything else in the box that you remember looking at? A Are you referring to the instructions for
2 3 4 5	sacrocolpopexy, would you also do or use a combination of procedures? A As necessary, yes. Q So that, for example, even though you're doing an abdominal sacrocolpopexy, you might at the	2 3 4 5	Q And were there any instructions or anything else in the box that you remember looking at? A Are you referring to the instructions for use?
2 3 4 5 6	sacrocolpopexy, would you also do or use a combination of procedures? A As necessary, yes. Q So that, for example, even though you're doing an abdominal sacrocolpopexy, you might at the same time also be doing a vaginal surgery or	2 3 4 5 6	Q And were there any instructions or anything else in the box that you remember looking at? A Are you referring to the instructions for use? Q Instructions for use or anything else that
2 3 4 5 6 7	sacrocolpopexy, would you also do or use a combination of procedures? A As necessary, yes. Q So that, for example, even though you're doing an abdominal sacrocolpopexy, you might at the same time also be doing a vaginal surgery or colporrhaphy or some other procedure?	2 3 4 5 6 7	Q And were there any instructions or anything else in the box that you remember looking at? A Are you referring to the instructions for use? Q Instructions for use or anything else that would have been within the box.
2 3 4 5 6 7 8	sacrocolpopexy, would you also do or use a combination of procedures? A As necessary, yes. Q So that, for example, even though you're doing an abdominal sacrocolpopexy, you might at the same time also be doing a vaginal surgery or colporrhaphy or some other procedure? A Typically not a colporrhaphy. That	2 3 4 5 6 7 8	Q And were there any instructions or anything else in the box that you remember looking at? A Are you referring to the instructions for use? Q Instructions for use or anything else that would have been within the box. A I don't recall.
2 3 4 5 6 7 8 9	sacrocolpopexy, would you also do or use a combination of procedures? A As necessary, yes. Q So that, for example, even though you're doing an abdominal sacrocolpopexy, you might at the same time also be doing a vaginal surgery or colporrhaphy or some other procedure? A Typically not a colporrhaphy. That wouldn't ordinarily be necessary to combine with an	2 3 4 5 6 7 8 9	Q And were there any instructions or anything else in the box that you remember looking at? A Are you referring to the instructions for use? Q Instructions for use or anything else that would have been within the box. A I don't recall. Q Did you modify or cut that mesh in any
2 3 4 5 6 7 8 9 10	sacrocolpopexy, would you also do or use a combination of procedures? A As necessary, yes. Q So that, for example, even though you're doing an abdominal sacrocolpopexy, you might at the same time also be doing a vaginal surgery or colporrhaphy or some other procedure? A Typically not a colporrhaphy. That wouldn't ordinarily be necessary to combine with an abdominal sacrocolpopexy.	2 3 4 5 6 7 8 9 10	Q And were there any instructions or anything else in the box that you remember looking at? A Are you referring to the instructions for use? Q Instructions for use or anything else that would have been within the box. A I don't recall. Q Did you modify or cut that mesh in any way?
2 3 4 5 6 7 8 9 10 11	sacrocolpopexy, would you also do or use a combination of procedures? A As necessary, yes. Q So that, for example, even though you're doing an abdominal sacrocolpopexy, you might at the same time also be doing a vaginal surgery or colporrhaphy or some other procedure? A Typically not a colporrhaphy. That wouldn't ordinarily be necessary to combine with an abdominal sacrocolpopexy. Q What other procedures would you ordinarily	2 3 4 5 6 7 8 9 10 11	Q And were there any instructions or anything else in the box that you remember looking at? A Are you referring to the instructions for use? Q Instructions for use or anything else that would have been within the box. A I don't recall. Q Did you modify or cut that mesh in any way? A Yes.
2 3 4 5 6 7 8 9 10 11 12	sacrocolpopexy, would you also do or use a combination of procedures? A As necessary, yes. Q So that, for example, even though you're doing an abdominal sacrocolpopexy, you might at the same time also be doing a vaginal surgery or colporrhaphy or some other procedure? A Typically not a colporrhaphy. That wouldn't ordinarily be necessary to combine with an abdominal sacrocolpopexy. Q What other procedures would you ordinarily combine with an abdominal sacrocolpopexy?	2 3 4 5 6 7 8 9 10 11 12	Q And were there any instructions or anything else in the box that you remember looking at? A Are you referring to the instructions for use? Q Instructions for use or anything else that would have been within the box. A I don't recall. Q Did you modify or cut that mesh in any way? A Yes. Q While you were in the operating suite?
2 3 4 5 6 7 8 9 10 11 12 13	sacrocolpopexy, would you also do or use a combination of procedures? A As necessary, yes. Q So that, for example, even though you're doing an abdominal sacrocolpopexy, you might at the same time also be doing a vaginal surgery or colporrhaphy or some other procedure? A Typically not a colporrhaphy. That wouldn't ordinarily be necessary to combine with an abdominal sacrocolpopexy. Q What other procedures would you ordinarily combine with an abdominal sacrocolpopexy? A A procedure for stress incontinence.	2 3 4 5 6 7 8 9 10 11 12 13	Q And were there any instructions or anything else in the box that you remember looking at? A Are you referring to the instructions for use? Q Instructions for use or anything else that would have been within the box. A I don't recall. Q Did you modify or cut that mesh in any way? A Yes. Q While you were in the operating suite? A At the scrub nurse's table, yes.
2 3 4 5 6 7 8 9 10 11 12 13 14	sacrocolpopexy, would you also do or use a combination of procedures? A As necessary, yes. Q So that, for example, even though you're doing an abdominal sacrocolpopexy, you might at the same time also be doing a vaginal surgery or colporrhaphy or some other procedure? A Typically not a colporrhaphy. That wouldn't ordinarily be necessary to combine with an abdominal sacrocolpopexy. Q What other procedures would you ordinarily combine with an abdominal sacrocolpopexy? A A procedure for stress incontinence. Q Now, I know that you told me that you used	2 3 4 5 6 7 8 9 10 11 12 13 14	Q And were there any instructions or anything else in the box that you remember looking at? A Are you referring to the instructions for use? Q Instructions for use or anything else that would have been within the box. A I don't recall. Q Did you modify or cut that mesh in any way? A Yes. Q While you were in the operating suite? A At the scrub nurse's table, yes. Q In other words, would you cut it after you
2 3 4 5 6 7 8 9 10 11 12 13 14 15	sacrocolpopexy, would you also do or use a combination of procedures? A As necessary, yes. Q So that, for example, even though you're doing an abdominal sacrocolpopexy, you might at the same time also be doing a vaginal surgery or colporrhaphy or some other procedure? A Typically not a colporrhaphy. That wouldn't ordinarily be necessary to combine with an abdominal sacrocolpopexy. Q What other procedures would you ordinarily combine with an abdominal sacrocolpopexy? A A procedure for stress incontinence. Q Now, I know that you told me that you used mesh when you were in Pittsburgh at the Magee-Womens	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q And were there any instructions or anything else in the box that you remember looking at? A Are you referring to the instructions for use? Q Instructions for use or anything else that would have been within the box. A I don't recall. Q Did you modify or cut that mesh in any way? A Yes. Q While you were in the operating suite? A At the scrub nurse's table, yes. Q In other words, would you cut it after you had the patient, if you will, on the table in the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	sacrocolpopexy, would you also do or use a combination of procedures? A As necessary, yes. Q So that, for example, even though you're doing an abdominal sacrocolpopexy, you might at the same time also be doing a vaginal surgery or colporrhaphy or some other procedure? A Typically not a colporrhaphy. That wouldn't ordinarily be necessary to combine with an abdominal sacrocolpopexy. Q What other procedures would you ordinarily combine with an abdominal sacrocolpopexy? A A procedure for stress incontinence. Q Now, I know that you told me that you used mesh when you were in Pittsburgh at the Magee-Womens Hospital in surgeries for abdominal sacrocolpopexy.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q And were there any instructions or anything else in the box that you remember looking at? A Are you referring to the instructions for use? Q Instructions for use or anything else that would have been within the box. A I don't recall. Q Did you modify or cut that mesh in any way? A Yes. Q While you were in the operating suite? A At the scrub nurse's table, yes. Q In other words, would you cut it after you had the patient, if you will, on the table in the course of the surgery after you had seen whatever
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	Page 110		Page 112
1	meeting, and occasionally the meeting of the	1	Q And can you tell me when you were doing
2	American College of Obstetricians and Gynecologists.	2	that residency from 1988 to 1992 it was a
3	Q And do you continue to attend those	3	four-year residency?
4	meetings?	4	A Yes.
5	A No.	5	Q during that time I assume you had
6	Q When is the last time you attended a	6	various rotations?
7	meeting of any of those organizations?	7	A Correct.
8	A I believe that would be in 2008.	8	Q In medical school itself, you would have
		9	had courses with respect to the anatomy; correct?
9	Q Did you, in fact, attend a meeting after		• • • • • • • • • • • • • • • • • • • •
10	you left the position as program director at the	10	
11	NIH?	11	Q Those would have included courses in
12	A No, I don't believe so.	12	pelvic anatomy?
13	Q The reason I'm asking, according to your	13	A Correct.
14	CV, you were there until 2007. So my question is	14	Q When you were doing your residency in
15	once you left that group, have you attended any	15	OB-GYN, did you have additional training and courses
16	professional organizational meeting?	16	in pelvic anatomy?
17	A No, I don't believe so.	17	A Not a course per se, but it was certainly
18	Q And it would be a fair statement then that	18	part of our curriculum.
19	you've not personally presented at any meetings	19	Q That's a major part of the body that
20	since that time?	20	gynecologists deal with on a regular basis; correct?
21	A Correct.	21	A Correct.
22	Q Let me see if I can go back, a little	22	Q And was it during the course of your
23	further back. You were at the Cleveland Clinic from	23	residency then that you were taught how to examine
24	1993 to 2000; correct?	24	patients for various conditions?
25	A Correct. I had my fellowship in '92 to	25	A Yes.
	Page 111		Page 113
1	Page 111	1	,
1 2	'93.		Q And I assume that during that residency
2	'93. Q That's what I want to go back to. As I	2	Q And I assume that during that residency you kind of covered a broad spectrum of
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	'93. Q That's what I want to go back to. As I appreciate your training, you went to college at the University of Maryland and finished there in 1983? A Correct. Q With a degree in microbiology? A Correct. Q Have you ever done any work in the field of microbiology since you finished? A No, not since I graduated from college. Q In other words, you've not been engaged in any laboratory or bench testing in any capacity with respect to the field of microbiology since you finished college? A Correct. Q Did you go directly from undergraduate to medical school? A Yes. Q And you finished medical school then in 1988? A Correct. Q And then you did a residency in OB-GYN? A Correct.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q And I assume that during that residency you kind of covered a broad spectrum of gynecology A Yes. Q and obstetrics? So you would have delivered babies? A During my residency, yes. Q You would have provided routine gynecologic care to patients? A Yes. Q Counseled on contraception? A Yes. Q Counseled on or treated women for menopausal issues? A Yes. Q And would you also have performed surgery during that course of your residency? A Yes. Q In what areas? A In obstetrics, in gynecology, in gynecologic oncology, and in the field of reproductive endocrinology and infertility, in which a lot of laparoscopic surgery is performed.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	'93. Q That's what I want to go back to. As I appreciate your training, you went to college at the University of Maryland and finished there in 1983? A Correct. Q With a degree in microbiology? A Correct. Q Have you ever done any work in the field of microbiology since you finished? A No, not since I graduated from college. Q In other words, you've not been engaged in any laboratory or bench testing in any capacity with respect to the field of microbiology since you finished college? A Correct. Q Did you go directly from undergraduate to medical school? A Yes. Q And you finished medical school then in 1988? A Correct. Q And then you did a residency in OB-GYN? A Correct. Q And that was at Hartford?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Q And I assume that during that residency you kind of covered a broad spectrum of gynecology A Yes. Q and obstetrics? So you would have delivered babies? A During my residency, yes. Q You would have provided routine gynecologic care to patients? A Yes. Q Counseled on contraception? A Yes. Q Counseled on or treated women for menopausal issues? A Yes. Q And would you also have performed surgery during that course of your residency? A Yes. Q In what areas? A In obstetrics, in gynecology, in gynecologic oncology, and in the field of reproductive endocrinology and infertility, in which a lot of laparoscopic surgery is performed. Q So when you say in obstetrics, that would
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	'93. Q That's what I want to go back to. As I appreciate your training, you went to college at the University of Maryland and finished there in 1983? A Correct. Q With a degree in microbiology? A Correct. Q Have you ever done any work in the field of microbiology since you finished? A No, not since I graduated from college. Q In other words, you've not been engaged in any laboratory or bench testing in any capacity with respect to the field of microbiology since you finished college? A Correct. Q Did you go directly from undergraduate to medical school? A Yes. Q And you finished medical school then in 1988? A Correct. Q And then you did a residency in OB-GYN? A Correct.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q And I assume that during that residency you kind of covered a broad spectrum of gynecology A Yes. Q and obstetrics? So you would have delivered babies? A During my residency, yes. Q You would have provided routine gynecologic care to patients? A Yes. Q Counseled on contraception? A Yes. Q Counseled on or treated women for menopausal issues? A Yes. Q And would you also have performed surgery during that course of your residency? A Yes. Q In what areas? A In obstetrics, in gynecology, in gynecologic oncology, and in the field of reproductive endocrinology and infertility, in which a lot of laparoscopic surgery is performed.

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	Page 114		Page 116
1	A Yes.	1	pharmacological agents or surgery, to treat that
2	Q Did you perform any surgeries for stress	2	condition?
3	incontinence?	3	A I'm not sure I understand your question.
4	A Yes.	4	Could you rephrase that?
5	Q At that point in time, this is 1988 to	5	Q Let me see if I can put it in this
6	'92, what procedures did you use to treat stress	6	perspective. Stress incontinence can pose a
7	incontinence?	7	significant burden to a woman?
8	A Primarily the Burch colposuspension.	8	A It can.
9	Q And that was an open abdominal surgery?	9	Q You agree with that?
10	A Preperitoneal, retropubic.	10	A Correct.
11	Q Any other procedures that were used to	11	Q And the condition itself is serious enough
12	treat stress incontinence?	12	that it's a condition that warrants the development
13	A Kelly plication.	13	of treatment for that condition?
14	Q Anything else?	14	MR. SLATER: Objection to the form.
15	A That's all I can remember.	15	You can answer.
16	Q Did you counsel with patients at that	16	THE WITNESS: Again, treatment is
17	point in time about stress incontinence?	17	based on the patient's symptoms.
18	A Yes.	18	BY MS. JONES:
19	Q And offer them alternative treatments to	19	Q I understand. I'm not trying to suggest
20	surgery?	20	that every patient would receive the same treatment.
21	- .	21	I'm simply saying that the condition itself is
22		22	. , , ,
	Q What alternatives did you discuss with the		serious enough and can pose, depending upon the
23	patients?	23	patient, a significant burden such that different
24	A Behavioral and lifestyle changes, fluid	24	alternative treatments are and should be part of the
25	modification, avoidance of certain fluids or even	25	physician's armamentarium to treat that condition?
	Page 115	4	Page 117
1	foods if that appeared to aggravate their problem,	1	MR. SLATER: Objection to the form.
2	things like that, and pelvic muscle exercises and	2	You can answer.
3	pessary use.	3	THE WITNESS: Shall I explain what
4	Q No question in your mind that stress	4	I'm struggling with?
5	incontinence can have an adverse effect on a woman's	5	BY MS. JONES:
6	lifestyle?	6	Q That's fine.
7	A I agree with that.	7	A Okay.
8	Q And that it can affect her from a	8	Q Do that and we'll see if we can straighten
9	psychosocial perspective, if you will?	9	it out.
10	A It can.	10	A Okay. If we understood the etiology of
11	Q That it can, you know, expose her to	11	stress incontinence, we could offer a specific
12	embarrassing circumstances that may lead some women	12	etiology-based treatment. Right now our treatments
13	to avoid participation in certain activities?	13	are empiric, which means we don't fully understand
14	A It can.	14	the etiology so we're not able to treat the root
15	Q It can certainly also affect a woman's	15	cause. And in a perfect world we would understand
16	sexual function?	16	the etiology fully, we would have an etiologic-based
17	A It can.	17	treatment, and we would be able to diagnose women
18	Q It is a condition that you as a	18	with the specific cause of her incontinence.
19	urogynecologist certainly believes warrants	19	Incontinence is only a symptom, the end result of
20	treatment?	20	whatever abnormality has preceded it that allows
21	A Treatment is based on the patient's	21	that symptom to occur.
22	symptoms.	22	Does that help you or help
		23	Q Let me see if we can approach it this way:
23	Q Understood. Treatment in the sense that	23	Q Let the see if we can approach it this way.
23			
	Q Understood. Treatment in the sense that women need to have various alternatives available, whether it's pelvic floor exercises or	24 25	Incontinence is the result of a dysfunction in the pelvic floor system; correct?

Page 118 Page 120 Not necessarily, not exclusively. A Age does not have a direct relationship 1 1 2 Q It can be? 2 with the development of incontinence. 3 3 Q Anything else that you can think of that's A It can be. 4 4 been theorized to have a direct development We know that various conditions and events 0 5 5 have been associated with stress incontinence; relationship? 6 Theorized? 6 correct? Α 7 A Correct. 7 0 That's fine. Answer the theorized. 8 8 O One of those is parity? I'm sorry. You Menopause has been theorized, medication 9 9 use, specific medications. have to sav --Q How about previous surgeries, 10 A Correct. I didn't realize that was the 10 11 end of the question. 11 hysterectomies? 12 Q Well, I meant to have a question mark 12 A That's controversial. I wouldn't say that there. One of those would be not only parity, but 13 13 it's been established as an association. it would include whether or not you'd had difficult O In your practice you said that you, as I 14 14 vaginal deliveries of children; correct? recall -- I'm not sure whether you said that you had 15 15 A It can. prescribed this or whether it was available, so let 16 16 O Well, for example, one of the thoughts is me ask you. Did you prescribe pessaries for use for 17 17 18 that during the course of childbirth you can develop 18 incontinence? whether it's vaginal tears or damage to the muscle 19 19 A Yes. 20 such that it may result in stress incontinence; 20 Did you prescribe pelvic floor exercises 0 correct? 21 21 for incontinence? 22 A Well, that's exactly what we don't 22 A Yes. 23 understand fully. Clearly there is an epidemiologic 23 Q That would be primarily the Kegel relationship between childbirth and the development 24 exercise? 24 of stress incontinence. To be able to say that this 25 25 Kegel is, yes, the eponym attached. Page 119 Page 121 specific injury in this specific woman led to the 1 Q I'm sorry? 1 2 development of stress incontinence, that we are 2 The eponym, the name of the doctor who described this in the literature. 3 3 unable to sav. Q Had you prescribed pharmacologic agents 4 Q There are also other conditions that have 4 5 been associated with stress incontinence; correct? 5 for treatment of stress incontinence? 6 6 A If I did, it would have been very rarely. A Correct. 7 7 Obesity? Very, very? Q Q 8 8 Correct. Very rarely. Α Α 9 Q Certain medical conditions? 9 Q And obviously you have performed the Burch 10 10 suspension? Correct. Such as diabetes, for example? 11 Q 11 A Correct. Q Any other type of treatment that you 12 12 either prescribe or surgical procedure that you 13 What are the other explanations that have 13 been associated from an epidemiological standpoint perform for treatment of stress incontinence? 14 14 15 with stress incontinence? 15 A The Kelly plication and sling procedures MR. SLATER: By the way, I just want 16 and injection of bulking agents, Durasphere®, for 16 to place an objection. Obviously I'm not going to example, Contigen®. Those are the two names that I 17 17 18 tell her not to answer. And I understand the 18 can think of at the moment. plaintiffs had an SUI in their past so it can be 19 When did you use Kelly's plication 19 deemed relevant, but at some point I assume we're 20 techniques? 20 going to get to prolapse. Maybe. 21 21 Typically in an elderly patient with mild THE WITNESS: Previous surgery for to minimal symptoms where I felt their risks 22 22 incontinence, being female. 23 outweighed -- the risks of a different stress 23 24 BY MS. JONES: 24 incontinence operation outweighed the benefits for 25 25 the patient. Q How about age?

	Page 122			Page 12
1	Q	When I said "when," I was actually	1	partners used them.
2	thinkin	g in terms of time period.	2	Q And am I correct that when you were in
3	Α	Oh.	3	your residency, just the residency, '88 to '92, you
4	Q	Were you using that in your residency?	4	were doing the Kelly's plication and the Burch
5	Α	Yes.	5	procedure?
6	Q	So you would have used it '88 to '92. Did	6	A And also the Marshall-Marchetti-Krantz,
7	you co	ntinue to use that throughout the time you	7	another retropubic suspension.
8	were p	oracticing?	8	Q At the time that you were doing these
9	Α	Yes.	9	surgeries, were there any published randomized
10	Q	When did you first begin to use the sling	10	controlled trials on any of these surgeries upon
11	proced	lures?	11	which you relied in terms of making your
12	Α	During my fellowship at the Cleveland	12	determination as to procedures to use?
13	Clinic.		13	A Not that I recall.
14	Q	That would have been 1992-93 then?	14	Q Let me see if I can turn to a little bit
15	Α	Correct.	15	different subject now and talk with you about
16	Q	At that point in time what materials were	16	prolapse. When did you first perform any surgery
17	you us	ing for slings?	17	for pelvic organ prolapse?
18	Α	,	18	A That would be in the first year of my
19	Q	And were there issues with recurrence with	19	residency.
20		ırgery?	20	Q In 1988?
21	Α	"Issues" meaning?	21	A Yes.
22	Q	Meaning that there were failures and that	22	Q And can you tell me what procedure it was
23	the co	ndition recurred?	23	that you performed?
24	Α	Yes.	24	A In general that I performed during my
25	Q	And do you know what that rate of	25	residency?
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recurrence was?
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A No.

Q I think you mentioned earlier today that at some point you used cadaveric tissues?

A I did not mention that. That had been used in -- at Magee-Womens Hospital. I did not use that material myself.

Q Why did you choose not to use that material?

A I didn't believe it was effective.

Q You didn't believe it was effective in the sense of providing long-term stability?

A Providing a long-term -- I don't like the word "stability," but a long-term solution for the patient's symptoms.

Q Were there also safety issues associated with cadaveric tissues?

A I don't believe that was to the extent of being clinically relevant. I think those were primarily theoretical.

Q The cadaveric tissues were used at Magee; is that correct?

23 A Correct.

Q Were they used at the Cleveland Clinic?

A I didn't use them. I don't recall if my

Q Yeah. In all fairness, what I want to talk with you about is what you did for treatment of prolapse during your residency versus what you did during the fellowship. I just want to have an understanding of the differences.

A All right. So in my residency we were trained to perform the sacrospinous ligament fixation as the most common procedure used for apical prolapse. In my fellowship and during my residency, anterior and posterior colporrhaphy.

Q Can I stop you there and then come back to the fellowship? At the time that you were taught to do the sacrospinal ligament fixation for apical prolapse, it was a vaginal surgery; correct?

A Correct.

Q What were the risks associated with that surgery that you would discuss with the patient?

A There are the general risks of -- that apply across the board pretty much to surgery in general: Bleeding; infection; if bleeding was excessive, the possibility of a transfusion; the risks associated with anesthesia; the possibility of a blood clot.

Specific to this type of procedure: 24 25 Recurrence of prolapse, voiding dysfunction, pain

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with intercourse. And by "voiding dysfunction" I can expand on that if you like.

Q That's fine.

A Okay. So temporary inability to empty the bladder fully, urgency, frequency, urinary tract infection. So that's what I would consider -- not urinary tract infection specifically, but in speaking to the patient about urinary issues, that's what I would talk with her about.

- Q Are there any other risks associated with sacrospinal ligament fixation that you can remember that you would talk with them about?
- A Organ damage in general. We're working very close to the bladder, the rectum, nerves. Blood vessels goes in the category of bleeding.
 - Q What about potential nerve damage?
 - A Potential nerve damage, correct.
- Q And when you indicated that you'd discuss the risks of painful intercourse, that's for I guess two or three different reasons: One, that that's a risk any time you're doing vaginal surgery; correct?
 - A Correct.
- Q Two, there's a possibility that you could affect either the length of the vagina or the introitus in the course of the surgery?

Q Were there any other risks that you would discuss with your patients when you were doing the sacrospinous ligament fixation?

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A I can't think of any others on the top of my head.

- Q Now, I stopped you because you were getting ready to say that that's what you did in your residency prior to 1992. And then that somehow changed or evolved when you began your fellowship or did your fellowship?
 - A Correct.
 - Q How did that evolve?

A In the group of surgeons they were performing a range of surgeries: Sacrospinous ligament fixation, uterosacral ligament suspension, iliococcygeus muscle suspension. Those were the three vaginal apical procedures.

- Q And I think you told us that you at least came to prefer the uterine --
- 20 A Uterosacral ligament suspension.
 - Q And why was that?

22 A I felt it provided good restoration of 23 the -- good correction of the vaginal prolapse and 24 it was relatively easy to teach to residents and

25 fellows.

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A I -- that's a possibility.

Q And the third aspect with the sacrospinal ligament fixation specifically is that that surgery, if you will, often pulled the vagina to one side or the other so that it affected its anatomical structure; correct?

A That is correct in a temporary sense. That's the result of surgery. For example, if it were placed in the patient's right sacrospinous ligament, the axis of the apex would be deviated to the right temporarily. As healing occurred, the axis was -- became restored to its normal direction.

Q As I understand this, and I promise you I have very basic understanding of it, the vaginal wall was affixed by a suture to the sacrospinous ligament?

A Yes.

Q And that meant that it was attached generally on one side, the right or the left, depending upon what the condition was you were treating it for?

A Actually it depended on whether the surgeon was right- or left-handed typically. But, again, that was a temporary deviation that would resolve itself in the course of healing.

Q Was it an easier surgery to perform than a sacrospinal ligament fixation?

A I don't know if I would qualify it as easier. It required less dissection in the very deep pelvis in the region of the sacrospinous ligaments, obviously. If we're not doing a sacrospinous ligament fixation or a Prolift® procedure, we're not needing to dissect around the sacrospinous ligaments.

Q And how would your discussions with the patients about the risk of the uterine sacrospinal suspension differ from what you discussed with patients with the sacrospinal fixation, ligament fixation?

A Uterosacral ligament suspension carries a slightly higher risk of ureteral injury because of where the stitches are placed. During surgery a cystoscopy is performed to check whether the ureters are still patent after the stitches have been tied down. And if they're not, one or the other, then we address that immediately and the patient doesn't have any additional morbidity from that point. But I would alert the patients that that was a possibility and we would not leave the operating room until we were sure that that was not the case.

Page 130 Page 132 Q Other than that, the other risks remain Q Have you seen it reported in the medical 1 1 2 the same? 2 literature associated with the uterosacral ligament 3 A Similar. 3 fixation? 4 Well, you essentially have the same 4 A Maybe I can back up and you can make sure 0 5 potential complications associated with the surgery 5 we're talking in the same way. You described in terms of the anesthesia complications, the voiding dysfunction that was -- can you say it 6 6 7 bleeding complications, perforation complications? 7 again? 8 All of those things would have remained the same? 8 I said ongoing. 0 9 9 Ongoing. A Yes. 10 Q It was also a vaginal surgery so there 10 Q It continues after just the immediate 11 would also be the risk of painful intercourse? 11 surgery. 12 Yes. 12 A Okay. So for how long? Α For any length of time. 13 During the time that you were practicing 13 medicine or surgery, throughout that period of time MR. SLATER: Objection. 14 14 did you continue to perform and treat the uterine 15 15 You can answer. THE WITNESS: In my experience the sacral ligament suspension procedure for treatment 16 16 of the apical prolapse? voiding dysfunction that occurs after uterosacral 17 17 18 A Yes. I would prefer to perform the 18 ligament suspension or sacrospinous ligament uterosacral ligament suspension unless I felt that fixation is in the range of days, occasionally 19 19 20 wasn't the best procedure for the patient. 20 weeks. Q And did you continue under other occasions 21 BY MS. JONES: 21 to use the sacrospinal ligament fixation? 22 22 Q Have you seen reported in the literature The sacrospinous ligament fixation, yes. voiding dysfunction that lasts longer than that? 23 23 Q I'm sorry. You mentioned the issues with 24 24 Longer than what? possible urethral damage in the course of the 25 25 Well, you just said that you generally saw Page 131 Page 133 1 it last days and sometimes weeks. I'm asking about surgery. 1 2 2 being reported that it's a longer lasting and Excuse me. Ureteral. 3 Q Ureteral. Was voiding dysfunction also a 3 perhaps permanent condition. potential complication of the uterine sacral 4 4 A I don't believe I've ever seen it recorded 5 ligament fixation? 5 as a permanent condition. 6 A Uterosacral ligament fixation, yes. Q Have you ever seen it being reported as 6 7 I'm going to get these terms right one of 7 longer lasting requiring subsequent treatment? A Not after an apical suspension. That 8 8 these days. 9 MR. SLATER: It's all right. Your 9 typically -- if that occurs, it's because an opening's two months away. anti-incontinence operation was performed at the 10 10 MS. JONES: I'm sorry? same time that requires treatment. 11 11 MR. SLATER: I said it's all right. 12 12 While you were in your residency, do you Your opening's two months away. You have plenty of have any idea how many sacrospinal ligament 13 13 fixations you performed? 14 time. 14 15 MS. JONES: I won't be able to 15 Α No. pronounce them then. Was it common in your residency for you to 16 16 perform pelvic floor repair surgery? In your MR. SLATER: Two months from 17 17 residency. 18 Wednesday. 18 What do you mean by "common"? BY MS. JONES: 19 19 Q Can you have ongoing voiding dysfunction 20 Well, how many pelvic floor repair 20 associated with sacrospinal ligament fixation? surgeries did you do during your residency? 21 21 That has not been my clinical experience. 22 22 A I don't know. Have you seen that reported in the medical Q Other than the sacrospinal ligament 23 Q 23 24 literature? 24 fixation, what other surgeries did you perform? 25 25 A Specific --A No.

Page 134 Page 136 four-month block with the gynecologic oncologists, 1 Q During your residency. 1 A Specific to prolapse? 2 2 working with them in their care of patients with 3 Q Prolapse, yes. gynecologic cancers; and a four-month block with the 3 4 A Uterosacral ligament suspension. I don't 4 division of reproductive endocrinology and 5 believe that included abdominal sacrocolpopexy. And 5 infertility, which, as I said before, is primarily it would include anterior and posterior laparoscopic surgery. 6 6 7 colporrhaphy. 7 Q So of that year of fellowship that you 8 8 O Do I understand that you do not have a did, if I'm correct, you had a four-month block in 9 recollection of doing the abdominal sacrocolpopexy 9 which you concentrated on pelvic floor during your residency? 10 10 reconstructive surgery that would have included 11 A Correct. 11 whether it's prolapse or stress incontinence 12 Q But you did do anterior and posterior 12 surgeries? 13 colporrhaphies? 13 A Correct. 14 A Correct. 14 And other than the fact that you began using the uterosacral ligament procedure for apical 15 Q Tell me what you understood the potential 15 complications and risks associated with reconstruction, was there any other differences in 16 16 anterior/posterior colporrhaphies to be. the surgeries that you performed --17 17 18 A They would be very similar to the risks of 18 MR. SLATER: Objection to the form. the uterosacral ligament suspension and the 19 19 You can answer. 20 sacrospinous ligament fixation. 20 BY MS. JONES: Q Any major differences that you can recall 21 Q -- as a fellow as opposed to a resident? 21 A I believe what I said is that uterosacral 22 in terms of what you would have discussed with your 22 23 patients? 23 ligament suspension was performed during my 24 A No, I don't think so. 24 residency, not as commonly as the sacrospinous 25 ligament fixation. I didn't experience training in Q Any other surgeries that you would have 25 Page 135 Page 137 performed during your residency for prolapse? 1 abdominal sacrocolpopexy until I reached my 1 2 2 A For prolapse? No, I don't think so. fellowship. 3 Q Then let's go into your fellowship. You 3 Q I apologize. When you got the training did your fellowship at the Cleveland Clinic. And for the abdominal sacrocolpopexy, at the time was 4 4 5 this was a one-year fellowship; am I correct? 5 mesh used in that procedure? 6 6 Α Yes. A Correct. 7 7 O Other than just the length of it, how did Q And can you tell me what kind of mesh was that fellowship differ from the fellowship at Magee 8 used in that procedure? 8 9 9 that you were involved with later on? Α No. A At Magee we were particularly interested 10 Q Do you know whether it was multifilament 10 in training academicians. And in order to provide 11 or monofilament? 11 12 them with the background to design and perform Α 12 high-quality research in their careers, they 13 13 Q Do you know whether it was polyethylene as obtained a Master's degree, a Master's of Science opposed to Mersilene® or Gore-Tex® or something 14 14 15 degree in clinical research as part of their second 15 else? 16 year of fellowship. I did not have that opportunity 16 It wasn't Gore-Tex®, but I don't know what Α in my fellowship so that was something I did a 17 17 it was. 18 little later. 18 Q Did you use mesh in all of your abdominal 19 sacrocolpopexies? 19 Q Anything else in terms of the actual 20 surgeries or patient care that you performed? 20 A Yes. A The setup of my fellowship was divided 21 21 And was that true throughout the time that you were performing surgeries? 22 amongst the three divisions in our department of 22 gynecology. So there was a four-month block in the 23 23 Α Yes.

When you would counsel a patient about

abdominal sacrocolpopexy, how would you counsel them

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division of benign gynecology, which was primarily

vaginal surgeons doing reconstructive surgery; a

Page 138 Page 140 about the risks of that surgery? perform hernia repair surgery going through your 1 1 2 A So all of the other risks that we've 2 oncology training? already discussed and, in addition to that, the 3 3 A In the four-month block with the 4 risks specific to mesh, mesh erosion, mesh 4 oncologists, I do recall performing hernia repairs 5 infection, the possibility of repeat surgery, if a 5 with them, yes. mesh complication occurred in which the mesh needed 6 Q And do you remember whether or not mesh 6 7 to be removed, and then the risks associated with 7 was used? 8 laparotomy, so bowel adhesions, small bowel 8 A It's a possibility. I cannot recall that obstruction, the need for a reoperation if that 9 9 with certainty. occurred, sometimes, not always, scarring, of 10 10 Q You think your first abdominal 11 course, you know, an abdominal scar. I think that's 11 sacrocolpopexy would have been in 1993? everything I can think of at the moment. 12 12 A Correct. Q Was there anybody specifically who trained At that time did you know whether any mesh 13 13 you on abdominal sacrocolpopexy? had been cleared by the FDA for use in abdominal 14 14 A Mark Walters. sacrocolpopexy? 15 15 A No. To my knowledge, Gynemesh® PS mesh 16 Is that the Mark Walters who's associated 16 17 with the International Academy of Pelvic Surgery? was the first to be cleared by the FDA for an 17 18 18 indication in pelvic reconstructive surgery. That 19 O And was he your principal mentor during 19 was in 2002. 20 your fellowship? 20 Q Do you know, Doctor, whether or not the 21 A I don't know that I would describe him as 21 mesh that you used in 1993 had been cleared by the 22 a mentor. He joined the staff as I -- no. Actually 22 FDA for any use? he joined the staff in August of 1993 just after I A I would assume so. 23 23 24 had finished my fellowship and joined the staff. 24 Q Do you know what use it was cleared for? And since I hadn't -- oh, I guess I misspoke then 25 25 Since I don't remember the specific mesh, Page 139 Page 141 1 because I've been describing the abdominal 1 I don't think you want me to guess. sacrocolpopexy as if it occurred in my fellowship. 2 2 O Do you know of any mesh cleared for use in But, no, he joined the year -- the month after I prolapse or stress incontinence surgery before 1996? 3 3 finished my fellowship. So that would have actually A I am not specifically aware of the dates 4 4 occurred in the following year. So I misspoke about 5 5 revolving around the FDA clearance of stress 6 that. Because the surgeons who were already there 6 incontinence products. 7 did not perform abdominal sacrocolpopexy. I would 7 O You're not aware of any mesh being cleared for use in pelvic reconstructive surgery before 8 describe him as a colleague. 8 9 Q Was it Dr. Walters that introduced the use 9 Gynemesh® PS? 10 of abdominal sacrocolpopexy at the Cleveland Clinic 10 MR. SLATER: Objection. 11 then? THE WITNESS: Correct, that is my 11 12 12 understanding. A Yes. 13 Q Prior to doing your first abdominal 13 BY MS. JONES: sacrocolpopexy, had you done any surgery using mesh? Q The use of mesh in abdominal 14 14 A The only possibility I can think of, and 15 15 sacrocolpopexy was a use that was developed by I'm not certain of this, but it would be with the physicians; correct? 16 16 oncologic surgeons if they had an abdominal 17 A I would assume so. 17 18 reconstruction from a hernia or some other 18 Historically there had been abdominal postoperative event; otherwise, the answer would be 19 19 sacrocolpopexy performed without using mesh, had 20 20 there not? no.

A Problems?

Q And there had been some problems with the

use of other tissues like the autologous tissues or

other graft tissues associated with it; correct?

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24

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A Correct.

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you?

You yourself don't have any recollection

Not by myself. It would be oncologists.

of doing any hernia repair surgery, do you, or do

Q I understand. My question is did you

Page 144 Page 142 Problems with recurrence? them how long it was before they would return to 1 Q 1 2 2 their normal lifestyle, whether it's work, Α Yes. 3 activities, whatever, how would you counsel them? And one of the reasons that the doctors 3 4 4 MR. SLATER: Objection; vaque. resorted to the use of mesh was to provide a better 5 5 anatomical repair with less recurrences; is that You can answer. 6 THE WITNESS: I would counsel her 6 correct? 7 What do you mean by a "better anatomical 7 that she should expect to be off work in the Α 8 repair"? 8 neighborhood of six to eight weeks. 9 9 BY MS. JONES: Q Well, you tell me why you used mesh in 10 abdominal sacrocolpopexy. 10 Q And what would you tell her about how long 11 Because it was the best alternative at the 11 it would be before she could drive? 12 12 A Drive? That's variable. I would time. 13 And why was it the best alternative at the 13 recommend to patients they not be taking pain Q 14 time? 14 medication -- they should get to the point in their A Because typically the vagina isn't long recovery when they are no longer in need of taking 15 15 enough to reach the sacrum by itself, so you need a pain medication before they begin driving. 16 16 bridging material. And use of materials such as --O And how long would it be that you would 17 17 18 autologous materials required harvest of a large 18 tell someone that they would need to avoid exercise, amount of natural tissue from the patient, so that's 19 for example? 19 20 a downside. And then other materials, Unigraft 20 A Six to eight weeks and once I had checked materials, had issues with increased recurrence of them twice usually in the office before releasing 21 21 22 prolapse. 22 them to that kind of activity. 23 Q There obviously was some morbidity 23 O And how long should they avoid 24 involved with patients from the stripping of the 24 intercourse? 25 fascia in preparing the autologous tissue; correct? 25 A Similar range, six to eight weeks and Page 143 Page 145 Correct. 1 until I had seen them. 1 Α 2 O Forgive me, Doctor, I think I asked this 2 O If you were in contrast advising a patient 3 question, but I can't remember. In terms of 3 who was having a colporrhaphy, how long would you tell her it would take her to recover? 4 discussions of the complications with the patients, 4 5 and you're talking about the abdominal 5 MR. SLATER: Objection. 6 sacrocolpopexy, the complications that you would 6 You can answer. 7 discuss were essentially the same as with the other 7 THE WITNESS: Six to eight weeks. surgeries that we've already discussed plus the ones 8 8 BY MS. JONES: involving mesh that you described; correct? 9 9 Q And would you tell her on all of the other 10 A Correct; and the risks specific to the 10 issues exactly the same as you would say on the abdominal approach. abdominal sacrocolpopexy? 11 11 The risks specific to the abdominal 12 12 Correct. 13 approach in addition to the scarring and so forth, 13 Q How long would you tell her she'd be in it's an open surgery that takes longer to heal, for 14 14 the hospital? 15 example, and generally it's a longer surgery than 15 Α Usually two days. some of the others, is it not? How long was somebody in the hospital with 16 16 No, I don't agree with that. abdominal sacrocolpopexy? 17 17 18 You do agree that it generally takes 18 A Usually two days. patients longer to recover from the abdominal At the time that you started using mesh in 19 19 sacrocolpopexy than from a vaginal surgery? 20 the abdominal sacrocolpopexy, were there any 20 randomized clinical controlled trials regarding the 21 A Well, can you be more specific about what 21 22 you mean by recovery? Do you mean return to work? 22 use of mesh in that surgery? What do you mean? Compared to what? 23 23 24 Q Well, if you were to counsel a patient on 24 Compared to using it without. Were there 25 abdominal sacrocolpopexy and you were going to tell 25 any randomized controlled clinical trials of which

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Page 146
                                                                                                              Page 148
    you were aware of involving abdominal sacrocolpopexy
                                                                colleagues in our division and our fellows and
                                                            1
2
    when you started using mesh in 1993?
                                                                residents. And then in 1999 I began working with
                                                            3
3
        A No.
                                                                the NIH.
4
           Am I correct, Doctor, if you know, that
                                                            4
                                                                    Q Well, let me see if I can break this down
        Q
5
                                                            5
    mesh had actually been used in abdominal
                                                                a little bit. When you took the Master's of Science
    sacrocolpopexy by surgeons since the 1970s?
                                                                degree, did you take a leave of absence to go and
6
                                                            6
7
        A No, I don't know when abdominal
                                                            7
                                                                get that degree?
8
    sacrocolpopexy with mesh began to be used.
                                                            8
                                                                    A No.
           Is this a good time for a break?
9
                                                            9
                                                                    Q Did you attain that by a correspondence
              MS. JONES: Okay.
                                                           10
                                                                school? How did you obtain that degree?
10
11
              MR. SLATER: Sure.
                                                           11
                                                                    A University of Michigan has a special
                                                                arrangement. They call it on job/on campus for
12
              (Short recess.)
                                                           12
                                                                people who travel in -- they have local people, too,
    BY MS. JONES:
13
                                                           13
                                                                but who can travel in from other states where the
14
        Q Doctor, are you currently licensed to
                                                           14
    practice medicine?
                                                                classes are held from Thursday to Sunday one day a
15
                                                           15
                                                                month -- excuse me -- once a month. And in that way
       A No.
                                                           16
16
17
        Q Do you know when you were last licensed?
                                                                the Master's is completed with its full credits in
                                                           17
18
    Would it have been 2006?
                                                           18
                                                                just under two years.
        A No. I believe I carried my license
                                                                    Q All right. So from '97 then to '99 you
19
                                                           19
20
    through to the end of 2007.
                                                           20
                                                                were spending four days a month working on your
        Q Have you attended any continuing medical
                                                                Master's at -- was that at Ann Arbor?
21
                                                           21
22
    education courses since that point in time?
                                                           22
                                                                    Α
                                                                       Yes.
23
       A No.
                                                           23
                                                                    Q
                                                                       And you said your practice was a general
24
        Q Are you Board-certified in any specialty?
                                                           24
                                                                gynecology practice?
25
           No. I was Board-certified in obstetrics
                                                                    A Yes.
                                                           25
        Α
                                                  Page 147
    and gynecology and I did not maintain that when I
                                                            1
                                                                       So that you were seeing women and were you
1
                                                            2
                                                                also doing obstetrics?
2
    discontinued my clinical practice.
                                                            3
3
        Q And were you ever Board-certified in any
                                                                    Α
                                                                       No.
    subspecialty of urogynecology?
4
                                                            4
                                                                    0
                                                                       Were you seeing women then in an office
5
        A No. At that time the Board had not yet
                                                            5
                                                                setting where you were counseling them on
    created subspeciality certification for individuals.
                                                            6
                                                                contraceptive, menopause, doing your annual checkups
6
                                                            7
7
    They were only certifying fellowship programs.
                                                                and so forth?
                                                            8
8
        Q When you were at the Cleveland Clinic
                                                                    A Correct.
    after you finished your fellowship, you stayed on,
                                                            9
                                                                    Q And was that the case, did you follow that
    can you describe for me what you did at the
                                                           10
                                                                practice throughout your tenure at the Cleveland
10
    Cleveland Clinic for that period from '93 to 2000?
                                                                Clinic?
11
                                                           11
                                                           12
        A Yes. My clinical practice started as a
                                                                    Α
                                                                       No.
12
    general gynecology practice. When I realized I
13
                                                           13
                                                                       When and how did that change?
    needed a stronger background in clinical research
                                                                       Within a couple of years, with the support
14
                                                           14
15
    design and performance, I attended the program at
                                                           15
                                                                of my chairman, he recognized my special interest in
                                                                pelvic floor disorders and we arranged that my
    the University of Michigan and obtained a Master's
16
                                                           16
                                                                clinical practice would focus on that to the
    of Science degree in clinical research design and
                                                           17
17
18
    statistical analysis.
                                                           18
                                                                exclusion of other general gynecology issues and
           And when I completed that, my chairman
                                                           19
                                                                regular well women care.
19
20 created a new position of director of clinical
                                                           20
                                                                    Q And who were the other members of the
    research in the department and appointed me as the
                                                           21
                                                                staff at the Cleveland Clinic who focused on pelvic
21
    first in that position. And in that role I advised
                                                           22
22
                                                                floor issues?
    the other faculty members and fellows and residents
                                                           23
                                                                   A Mark Walters; Lester Ballard,
23
    in designing and performing their own research. I
                                                                B-A-L-A-R-D; Delbert Booher, B-O-O-H-E-R.
24
                                                           24
    performed my research in conjunction with my
                                                           25
                                                                    Q And when you began, it would have been
25
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Page 150 Page 152 sometime then around 1995-96 that you began to move 1 What did that consist of? 2 into the urogynecology practice? 2 A four- to six-week rotation where the A Urogynecology had always been a portion of 3 3 medical students -- actually obstetrics and my practice. It was at that time that it became 4 4 gynecology was four to six weeks. So the gynecology 5 exclusive -- my practice was exclusive to 5 portion would be roughly half of that. And they urogynecology. 6 would attend office with us, they would come to 6 7 Q At that point in time then is it fair to 7 surgery with us, see postoperative patients in the 8 say while you were at the Cleveland Clinic that you 8 hospital, attend lectures, and so on. 9 had done colporrhaphies? Q Were you involved prior to obtaining your 9 10 Α Yes. 10 Master's in research? 11 Q Sacrospinal ligament fixation? 11 Yes. Α Sacrospinous ligament fixation, yes. 12 12 Q What percentage of your time was spent in The uterosacral ligament suspension? 13 0 13 research? 14 A Yes. 14 A I think at that time I had a half day that 15 Q The abdominal sacrocolpopexy? was not otherwise in the office or in the OR, in the 15 16 Α 16 operating room. 17 O And that half day would have been when you Q Various sling or Burch procedures for 17 18 stress incontinence? 18 did whatever research you were engaged in? 19 19 A And what would otherwise be called spare A Yes. 20 Q Anything else? 20 time. A The Kelly plication and paravaginal 21 21 Did you have any administrative Q 22 22 responsibilities? repair. Q While you were at the Cleveland Clinic, do 23 23 A Not at that time. 24 you have any idea how many prolapse surgeries you 24 In 1999 when you took the position as program director for the pelvic floor disorder 25 performed? 25 Page 151 Page 153 A I would estimate in the range of 1,500 to 1 program, at that point in time when you were at the 1 2 2,000. 2 Cleveland Clinic you were spending 25 percent of Q Between '93 and 2000? your time I think doing that is what you testified; 3 3 4 correct? 4 Α Yes. 5 Q And what type of procedure did you perform 5 Α Yes. the greatest number of? 6 Q And that would have been further from '99 6 7 7 A For apical prolapse, it would be the until 2001 when you left the Cleveland Clinic? 8 8 uterosacral ligament suspension. For anterior and Α Yes. 9 9 posterior vaginal prolapse, it would be anterior and Q And why did you leave the Cleveland posterior colporrhaphy. 10 Clinic? 10 Q I didn't ask the question very well 11 There was an opportunity at the University 11 obviously. I'm trying to figure out in terms of 12 of Pittsburgh. As I mentioned earlier, the chairman 12 your patient population, did you treat patients more very much wanted to develop a fellowship program and 13 13 for apical prolapse or for anterior and posterior the faculty who were there didn't really have the 14 14 skill set or the experience to make that happen. 15 prolapse? 15 A I really can't tell you that. 16 Q At any time while you were practicing 16 medicine, Doctor, did you have your privileges Q Do I recollect correctly that you said 17 17 18 that you did surgery one day a week at the Cleveland 18 suspended? 19 19 Clinic? Α 20 20 A Typically, yes. Q Did you ever have your license restricted On your CV you say that you were also 21 21 in any way? involved in the education of medical students in 22 22 Α core rotation obstetrics and gynecology while you Other than the one lawsuit that we talked 23 23 0 about earlier, have any other claims filed against 24 were there? 24 25 25 A Yes. you?

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Page 154 1 A No. 2 Q If I look at your CV, there's a reference 3 to 2001 a Presidential SGS Member Prize Award. 4 What was that? 5 A Could you just remind me where you are? 6 Q It's on Page 3. 7 A Oh, yes. So that was a research award for 8 a presentation. I believe the 2000 one was the anterior colporrhaphy trial. And the one in 2001, I can match it to my abstract if you want me to. I 10 11 don't remember off the top of my head what that was for. Okay. So the anterior colporrhaphy trial was 12 I was awarded -- myself and my co-authors were 13 awarded that first prize, Presidential SGS Member 14 15 Prize in 2001. And then in 2000 myself and 16 Dr. Walters were awarded the 1st Prize Presidential SGS Member Prize for our study about the 17 18 cost-effectiveness of urodynamic testing. Q While you're looking at that, first of 19 20 all, both of those prizes would have been joint 21 awards to whoever the authors were on those papers? 22 A Yes. 23 Q And then the next one is Best Poster 24 Presentation. Tell me what that topic was in 1999. 25 A Okay.

Page 156 you have that you were a member of the editorial board of Obstetrics & Gynecology. Obstetrics & Gynecology is the publication of ACOG?

- A Yes.
- Q And that publication of ACOG would go to all of the members of the American College of Obstetrics and Gynecology?
 - Yes.
 - 0 That is a peer-reviewed journal?
- Α
- 0 Can you tell me how you as an editor on that journal were involved in the peer review?

A Yes. As a member of the editorial board, we have a greater role in the review of manuscripts. A manuscript is typically sent out to two or three reviewers. One reviewer will be a member of the editorial board and the other one or two reviewers will be a member of the OB-GYN community. And we also participated in the editorial board meetings where we discussed matters of editorial policy, et cetera.

Let me ask this question: If somebody is a researcher and they complete a study, they submit a paper for publication, does that paper automatically go out to peer reviewers?

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MR. SLATER: Best poster? I remember that. First grade. I always made the best poster. THE WITNESS: Science fair my sister said.

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Okay. That was for our study on sexual function in women before and after surgery for pelvic organ prolapse and urinary incontinence. BY MS. JONES:

Q And then you have the ACOG/Ethicon Research Award for Innovations in Gynecologic Surgery in 1996?

A Yes. That was for the research proposal that turned out to be the anterior colporrhaphy trial.

- Q And was that awarded to you as well as the folks that were the co-authors of the --
 - A The institution, to the Cleveland Clinic.
- And then if you look down here, the Prize Paper, American Urogynecologic Society, in 1996, what was that?
- A I believe that was the "Sexual function and vaginal anatomy in women treated with sacrospinous ligament suspension and pelvic reconstruction."
 - Q If we look under "Professional Service,"

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- 1 A It does at the Journal of Obstetrics & 2 Gynecology, yes. 3
 - Q So it automatically goes out to peer reviewers and then those peer reviewers, are those peer reviewers chosen as ideally people that are, quote, expert in the field of the subject matter of the paper?
 - A I think it depends. When there are two or three reviewers, I think the editor would decide to send the manuscript to one or two people who are expert in the field and perhaps an additional reviewer who's not necessarily an expert to make sure that it's explained well enough to someone who's not an expert.
 - Q And the purpose of that peer review, though, is more than just looking at it from the standpoint of whether or not it reads well?
 - A Yes.
 - Its purpose is also to ensure as best they can the validity of the scientific methods and conclusions that are described in the paper?
- A I would describe it as a process of evaluation of the scientific methods, data analysis, 24 presentation, conclusions drawn.
 - Q And following that peer review, those peer

Page 158 Page 160 reviewers will send their comments back to the 1 1 Α No. 2 editorial board or do they go directly to the author 2 On your CV it says that you were a peer 3 3 of the paper? reviewer on all of these at present? 4 A No. To the editor. There's an editor and 4 A Correct. 5 5 Can you tell me when the last time you then there are associate editors in the broad 6 peer-reviewed an article for Obstetrics & Gynecology 6 specialty areas of obstetrics and gynecology. So 7 the reviewers' comments will go back to the 7 was? 8 appropriate associate editor. And the main editor 8 I would estimate perhaps a year ago. 9 could be involved, if necessary, deciding what the 9 That would have been 2011? 0 disposition of the paper would be, whether it would 10 10 Α 11 be rejected, rejected with possibility of rereview 11 Q Do you remember whether or not the article if it were resubmitted, or acceptance. 12 12 that you peer-reviewed was published? O So once it goes out to the peer reviewers, 13 13 No. I don't. it's returned to the editor and at that point in 14 14 What about the American Journal of time the editor can either reject it or can send it 15 15 Obstetrics and Gynecology; when's the last time you back to the authors to make corrections? peer-reviewed something there? 16 16 A To receive the feedback from the reviewers A That might be a little longer, perhaps 17 17 18 and make changes as the authors decide. 18 2010. I don't remember exactly. Q What about the American Journal of Q And then it would be resubmitted to the 19 19 20 editorial board and is it sent back to the peer 20 Gastroenterology? reviewers? 21 A That would be less. That would even be a 21 22 A Typically. 22 little farther away, maybe 2008. O How about the British Journal of 23 Q And then it's sent back to the editorial 23 24 board that makes the final decision on acceptance or 24 Obstetrics and Gynaecology? A I don't remember exactly. A couple of 25 publication? 25 Page 159 Page 161 Yes, acceptance or rejection. 1 years I would guess. 1 2 2 O And so before it is ultimately accepted O How about the Cleveland Clinic Journal of 3 for publication, assuming there have been any 3 Medicine? changes to be made, it's been sent out to the peer 4 4 A Again, I would guess a couple of years. 5 reviewers at least twice? 5 0 How about Diseases of the Colon & Rectum? 6 6 A couple of years. A Typically, yes. Α Q And that process applies to original 7 7 How about Evidence-based Obstetrics & 0 research that's submitted? 8 Gynecology? 8 9 A Yes. 9 A Probably a couple of years. 10 Q Does it apply to review articles that are 10 Q Gastroenterology? submitted? A Probably a couple of years. 11 11 International Urogynecology Journal? 12 12 Α That might be more recent, perhaps a year 13 0 Does it apply to letters to the editor? 13 or two ago. I'm not sure. 14 Α 14 15 Other than on Obstetrics & Gynecology, 15 How about the Journal of Pelvic Surgery? Q have you served on the editorial board of any other Probably a couple of years ago. 16 16 Α How about the Journal of Reproductive peer-reviewed journal? 17 17 0 18 A Not on the editorial board, no. I've been 18 Medicine? a peer reviewer -- I think that's on the next 19 19 Probably a couple of years ago. page -- yes, of several other journals. 20 How about the Journal of Urology? 20 Q And when you say you were a peer reviewer, Probably a couple of years ago. 21 21 Α How about the Journal of Women's Health? 22 they may just periodically call you and ask you to 22 Q look at some paper that's been submitted? Probably a couple of years ago. 23 23 Α How about the Medical Science Monitor? 24 A Correct. 24 Q 25 25 Probably a couple of years ago. And are you compensated for that? Q Α

Page 162 Page 164 Q How about the Neurourology and had not used mesh at all; correct? 1 1 2 **Urodvnamics?** 2 A I don't know that. 3 3 A Probably a couple of years ago. Q What I'm trying to ask, was there anything 4 Q Fair to say you have not peer-reviewed any about your experience with the TVT® that caused you 4 5 5 to abandon the use of the TVT® or was it that you iournal article in 2012? 6 6 went to Magee and they were using the autologous A Correct. 7 Q If I remember your testimony, you're not 7 tissue and you just adopted that? 8 sure that you peer reviewed anything in 2011? 8 A I think it's always preferable to perform 9 9 A Correct. a surgery without mesh. 10 Q The last time you remember peer-reviewing 10 Q Prior to that point in time, had you had 11 anything would have been 2010? 11 any adverse experiences with the TVT® surgery that led you to abandon it? 12 A I'm not sure. 12 A Not with my patients, not in patients who Q Could it have been longer ago than that? 13 13 It could have been. I personally operated on, but as a referral center 14 14 we are referred patients who have complicated 15 Q Other than in the case of abdominal 15 problems. So I have removed TVT® slings for mesh 16 sacrocolpopexy, have you ever taught a resident or 16 fellow about the use of mesh in pelvic floor repair complications. 17 17 18 surgery? 18 Q Did you do that in the Cleveland Clinic? A Well, as I said, at or around the time I 19 Yes. 19 Α 20 was leaving the Cleveland Clinic, we were beginning 20 Did you do that at Pittsburgh? Q to use the TVT®. So in that setting, yes. 21 No. The community was not using mesh to 21 Q And I think you told us you did not use the degree that was occurring in Cleveland, I 22 22 the TVT® in Pittsburgh? believe. So I don't recall personally seeing 23 23 24 Correct; except -- no. Excuse me. Never 24 referrals for mesh complications. 25 Q You told us that when you began using mesh 25 mind. Page 163 Page 165 Q Have you used TVT® to correct stress 1 for abdominal sacrocolpopexy, that you would discuss 1 2 incontinence at any time after you left the 2 with your patients the complications potentially 3 Cleveland Clinic? 3 associated with mesh? 4 Α No. 4 Α Yes. 5 On how many occasions did you use it at 5 Q And that would be including mesh exposure 6 the Cleveland Clinic? 6 or erosion? 7 7 A I can give you a range of perhaps 10 to Α 8 8 20. 0 Mesh contraction? 9 Q And that would have been shortly before 9 you left? 10 Q I think you mentioned the possibility of 10 infection? 11 A Correct. 11 Q And am I correct that you never used other 12 12 Infection, ves. Α 13 mesh slings other than the TVT®? 13 0 Anything else that you would counsel your patients on? 14 A Correct. 14 15 Q And did you use only the TVT® or did you 15 The possibility of a fistula development, use the TVT® Obturator? enterovaginal or rectovaginal. 16 16 A No, not the TVT® Obturator. O And was that true, I mean your counseling 17 17 18 And was there a reason that you did not 18 of your patients about that group of potential use the TVT® once you moved to Pittsburgh? complications remained true from 1993 throughout 19 19 A The experience at Pittsburgh, at the 20 your practice? 20 University of Pittsburgh Magee-Womens Hospital, was 21 Α Yes. 21 in using slings of rectus fascia. And I agreed with 22 22 While you were practicing, did you that practice and that's how I performed slings. maintain any database or registry of the patients on 23 23 whom you performed surgeries? 24 Q So at the time that you joined the staff 24 25 at Magee, they were using the autologous tissue and 25 A No, not unless they were involved in one

Page 166 Page 168 of our specific research protocols. potential causes of prolapse? 1 1 2 Q I know. I was trying to separate that out 2 Okay. Again, we talked earlier about not and ask whether or not you kept a personal list or completely understanding the etiology of stress 3 3 4 file of surgeries that you performed and so forth. 4 incontinence. The same thing applies to 5 5 understanding the etiology of prolapse. My No. Α 6 understanding of the development of prolapse begins 6 Q We have been talking about prolapse. 7 Would you consider prolapse to be a pelvic floor 7 with some element of pelvic muscle dysfunction that 8 8 leads to undue strain on the connective tissue disorder? 9 A Yes. 9 attachments to the vagina they were not by nature 10 Q And would you consider prolapse to be a 10 designed to withstand, and so over time those 11 pelvic floor disorder that can pose serious problems connective tissue attachments can stretch or 11 12 for women? 12 possibly break resulting in loss of support to the vagina. And since the other organs in the pelvis --13 13 A It can. the bladder, the uterus, the rectum -- rely 14 O As we talked about with incontinence, it 14 can also affect a woman's lifestyle or confidence? primarily on the vagina for support, when the vagina 15 15 loses support, the pelvic organs prolapse. 16 A It can. 16 O You said that it was your understanding 17 O Can be an embarrassing situation? 17 18 Are you comparing incontinence and 18 that it was a disorder of the muscles in the pelvic prolapse or just restricting --19 19 floor? 20 Q No, not at all. I'm just asking in 20 A A dysfunction of the pelvic muscles. general. I was really referring back to what we had 21 And the dysfunction of the pelvic muscles 21 22 talked about earlier only, not necessarily comparing 22 can be painful? 23 the two. 23 A Not the type that leads to prolapse. In 24 A Okay. Yes. Then the answer is yes. 24 the way I'm speaking of dysfunction at this moment, 25 it's a weakness or a laxity, a loss of tone or Q The answer is, yes, that it can be 25 Page 167 Page 169 embarrassing. Can it affect either the ability or 1 strength, not a painful condition. 1 2 2 desire for sexual relations? O Let me just ask the guestion and understand that. Has pelvic muscle dysfunction been 3 What do you mean by "ability"? 3 Well, can it affect sexual function? associated with pelvic pain? 4 Q 4 5 A It can affect sexual function. 5 "Dysfunction" is a very broad term. I 6 6 prefer to speak specifically of what I believe is Q Can it affect sexual satisfaction? 7 7 affecting the pelvic muscles. Are they hypertonic? A It can. 8 8 Is that a reason for pain? To my understanding, Can prolapse impair bowel movements 0 9 depending on the type of prolapse? 9 laxity associated with prolapse does not cause A It can. 10 pelvic muscle pain. 10 11 Q Can it affect urinary incontinence? Are other forms of pelvic muscle disorder, 11 12 whether it's dystonia or something else, associated 12 A Can you specify that? 13 Q Well, can it affect either urinary 13 with pelvic pain? incontinence or urinary retention? A Yes. Hypertonicity, spasm, myalgia, a 14 14 15 A I don't know that it affects urinary 15 number of terms that, yes, are associated with pain. incontinence. Urinary retention can be associated Q And those disorders that are associated 16 16 with very advanced prolapse. with pelvic pain are disorders that are seen and 17 17 18 Q In terms of the symptoms that a woman 18 treated by gynecologists and urogynecologists? often reports, she might report a feeling of pelvic 19 19 heaviness or a bulge from time to time? 20 Now, if we're looking at the factors 20 associated with prolapse, they may be genetic 21 Yes. 21 Α factors, for example? 22 O Have there been or are there risk factors 22 associated with prolapse? 23 Possibly. 23 Α

So, for example, family histories have

been associated with prolapse?

24

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24

25

A I don't think I understand your question.

Q What factors have been identified as

Page 170 Page 172 general prolapse, you can pick any kind you want, I 1 Α Yes. 1 2 Q There's some thought that connective 2 assume that you would agree with me, and I think this is what you've said, that any consultation and 3 tissue diseases or other diseases might be 3 4 associated with prolapse? 4 treatment has to be geared specifically to the 5 5 Might be. patient's condition? Α 6 6 Q Obesity has been associated with prolapse? A To the patient's symptoms. 7 7 O Patient's symptoms. Α 8 O Childbirth has been associated with 8 9 9 prolapse? Q And as a surgeon when you're advising a 10 A Yes. 10 patient or consulting with them on the alternatives 11 O Have conditions that are stress or strain 11 for treatment of those symptoms or conditions, it's important to discuss the broad range of those on the musculature, for example, constipation, been 12 12 possible alternative treatments? 13 associated with prolapse? 13 A To my understanding, that is more 14 14 Α Yes. theoretical than evidence-based. I think it's 15 15 And in discussing those treatments with a plausible, but I don't think it's well supported by patient, depending upon her condition, among the 16 16 alternative treatments that would be considered 17 the literature. 17 18 Q How about age being associated with 18 would be, one, doing nothing and just observing the 19 19 condition for a while to see how it developed; prolapse? 20 20 correct? A Age, yes. 21 Q Menopause? 21 A Correct. 22 A Menopause, again, theoretical but not well 22 Q Two, suggesting the use of certain pelvic floor muscle exercises --23 23 supported. Q How about smoking? 24 Correct. 24 Α Theoretical, not -- I don't believe I've 25 25 Q -- to strengthen the muscles; correct? Page 171 Page 173 seen literature supporting an association between 1 Α Correct. 1 2 smoking. Chronic coughing is often listed. And, 2 Three might be the use of pessaries? 0 again, that's something that's more anecdotal and 3 3 Correct. 4 not, to my knowledge, well supported in the 4 And four might be the use of different 5 literature. 5 surgeries; correct? 6 6 Q Chronic coughing has been associated much A Correct. I would also add behavioral and 7 7 lifestyle changes. like constipation has in the sense of it putting stress or strain on the pelvic musculature? 8 8 Q And when you say "behavioral and lifestyle 9 A Correct. 9 changes," tell me what changes you would include 10 Q Are there other identified factors that 10 within that. have been associated with prolapse? A I would inquire as to her bowel habit and 11 11 A Lifting, heavy physical work, that falls 12 ask her about things like straining; and if that's a 12 problem for her, to address that. Almost regardless into the category of the constipation and the 13 13 chronic coughing. Again, really anecdotal. of whatever other form of treatment she chooses, if 14 14 15 Q How about exercise? 15 any, I would want her to stop doing that, straining. A Yeah, that's a confounder. Obviously a Q And so to accomplish that would you 16 16 very general term. So there may be some exercises prescribe, for example, a laxative or some other 17 17 18 that are actually beneficial in terms of protecting 18 pharmacologic agent or how would you change that? or strengthening the pelvic floor and preventing or Change her eating habits? 19 19 ameliorating prolapse and then there may be 20 A Well, pharmacology would be one way to go. 20 Eating habits. You have to learn what the patient's 21 exercises that are -- have a relation with increased 21 22 intra-abdominal pressure and have that theoretical 22 already doing obviously to be able to suggest what association with prolapse. will work for her, what she's going to be willing to 23 23

24

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accept and so forth.

Q And as a surgeon when you counsel a

24

25

Q If a patient came to you with prolapse,

and just for our purposes right now let's say just a

	Page 174		Page 176					
1	patient about the different surgical alternatives,	1	Q Never reviewed prior to being engaged in					
2	one of the issues that would be important would be	2	this litigation any of the marketing materials for					
3	for the surgeon to counsel with respect to	3	Prolift®?					
4	procedures with which he or she is comfortable and	4	A Just what I would see in the journals, you					
5	familiar; correct?	5	know, as I'm reading them.					
6	A Correct.		6 Q Never saw a surgery involving Prolift®?					
7	Q And if he or she is not comfortable or	7	5, 5					
8	familiar with doing a particular surgery that the	8	Q The surgical videos that you saw in the					
9	patient needs, then it would be appropriate to refer	9	context of this litigation?					
10	that patient elsewhere?	10	A Yes.					
11	A I agree with that.	11	Q Prior to being retained as an expert in					
12	Q So that as a practical matter, it's	12	this litigation, you had never seen a surgical video					
13	important in the course of discussing treatment of	13	5 , ,					
14	prolapse with a patient that the surgeon and patient		14 A Correct.					
15	together discuss all of the options for her	15	Q I think it's self-explanatory, but you've					
16	particular condition as well as determining whether	16	never observed a surgery where Prolift® has been					
17	or not or what type of surgery that particular	17	used other than on that video that you saw in the					
18	surgeon can or should perform?	18	context of litigation?					
19	MR. SLATER: Objection to the form.	19	A Correct.					
20	You can answer.	20	Q Have you participated, Doctor, in the					
21	THE WITNESS: Yeah, that's a long	21	professional educational programs of any					
22	question. I agree with the beginning part. I think	22	manufacturer of pelvic mesh other than Ethicon?					
23	I lost you at the end.	23	• • • • • • • • • • • • • • • • • • •					
24	BY MS. JONES:	24	professional education for Prolift®.					
25	Q You would agree with me that if a surgeon	25	Q I understand that. My question was not					
23	Q Tou would agree with the that it a surgeon	23	Q I understand that. My question was not					
	Dago 17E		Dago 177					
1	Page 175	1	Page 177					
1	does not feel comfortable with performing a	1	very artful. I apologize. Have you participated in					
2	does not feel comfortable with performing a particular surgical procedure, it would be	2	very artful. I apologize. Have you participated in any professional education program put on by any					
2	does not feel comfortable with performing a particular surgical procedure, it would be appropriate for that surgeon to refer the patient to	2	very artful. I apologize. Have you participated in any professional education program put on by any manufacturer of mesh used in pelvic floor repair?					
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4	Page 178	1	Page 180				
1	Prolift® preceptor?	1 2	5 5 1				
2	A Do you mean ever or specific to Prolift®	3					
3	precepting?		•				
4	Q Specific to Prolift®.	4	A No.				
5	A No.	5	Q Have you prior to being engaged in this				
6	Q Do you know Prolift® preceptors?	6	3				
7	A I know Vince Lucente.	7	published by a manufacturer? A Specific to prolapse or incontinence?				
8	Q Do you know anyone other than Vince	8	·				
9	Lucente?	9	Q Let's talk about specific to prolapse				
10	A Probably but I don't I can't pull out	10	first.				
11	any other names off the top of my head.	11	A No.				
12	Q Were you ever a Prolift® proctor?	12	, ,				
13	A No.	13	•				
14	Q Ever speak to a Prolift® proctor about	14					
15	Prolift®?	15	Q Tell me what surgical technique manual you				
16	A No.	16	Saw.				
17	Q Before being engaged as an expert in this	17	A The TVT®.				
18	litigation, had you ever read the Prolift®	18	Q Have you seen any surgical technique				
19	information for use?	19	manual ever published by any manufacturer other than				
20	A Instructions for use? No.	20 21	Ethicon? A Before this involvement?				
21	Q Instructions for use. I'm sorry.	22					
22	A No.		Q Before this involvement.				
23	Q Had you ever read the IFU for Gynemesh®	23 24	A No. O Today as you sit here have you seen any				
24 25	PS?	25	Q Today as you sit here have you seen any surgical technique manuals produced by AMS, for				
25	A No.	20	surgical technique manuals produced by AMS, 101				
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Page 182 Page 184 A I don't know but I can't say for sure not. Q And would the same thing be true for 1 1 2 MR. SLATER: One second. 2 sacrospinous ligament fixation, for example? 3 A Well, that -- yes, that would have been, 3 (Short recess.) 4 4 you know, as part of my initial hiring out of BY MS. JONES: 5 5 Q Doctor, when you did your training on fellowship. abdominal sacrocolpopexy, you said that you were 6 6 Q But it would have been --7 trained by Dr. Walters? 7 Α The chairman. My chairman. 8 8 The chair of your department or your A Yes. hospital would have been the one that credentialized 9 Was that in surgery, hands-on training? 9 Q you that said that you're allowed to perform these 10 Α 10 11 Q Did you do any work in a cadaver lab, for 11 surgeries? 12 example, to do that surgery, to learn to do the 12 A Well, we filled out the form together. Here are the list of procedures. You've done that? 13 surgery? 13 Yes. You're trained and experienced in that? Yes. 14 A No. 14 Q Were there any videos or DVDs available to So to my recollection, we did that together. 15 15 you to help you learn how to do that surgery? O You and the chairman? 16 16 17 A No. 17 Α Yes. 18 Q Did you see any slides or PowerPoint 18 0 But the chairman had to sign off on that, presentations about how to do that? if you will, before you were allowed to conduct 19 19 20 20 those surgeries in that hospital? 21 Q I guess that's almost 20 years ago. Maybe 21 A Correct. 22 they didn't have those at that time. Did you attend 22 Q Was that true of all of the surgeries that any lectures on how to do that surgery and under 23 23 you performed? what circumstances? 24 Yes. 24 Α 25 A I had exposure to abdominal 25 And was that true also at Magee when you Q Page 183 Page 185 sacrocolpopexy, the teaching of how to perform it, 1 went to Pittsburgh? 1 2 in my residency and in my fellowship, but in actual 2 A I don't remember that specifically, but I hands-on performing surgery under the supervision 3 imagine a similar process took place. 3 and guidance of Dr. Walters, that occurred in 1993. Q Generally it is the hospitals or the 4 4 5 Q When you said you had exposure during your 5 chairs of those departments there that authorize or 6 fellow -give the permission to surgeons to perform certain 6 7 7 A Residency and fellowship. surgeries; correct? 8 -- your fellowship and residency, was that 8 Α Yes. 0 9 in the form of lectures? 9 Doctor, have you ever talked with a A Yes; and textbooks. 10 patient who had mesh used for pelvic floor repair 10 Do you have any recollection of how many and recommended that they file a lawsuit? 11 11 cases you watched before you actually performed the 12 12 13 surgery? 13 0 I think you told us about your knowledge A No, I don't. of potential mesh complications. Have you ever 14 14 15 Q Was it more than one? 15 removed a Prolift®? 16 Α Yes. 16 Α No. Who credentialized you to allow you to do 17 0 17 Or any portion of the mesh of a Prolift®? 18 an abdominal sacrocolpopexy at the Cleveland Clinic? 18 Α A I don't recall if there was a specific 19 19 0 Have you ever treated a woman who had a 20 process for that. It would have been my chairman if 20 Prolift®? that process -- I certainly remember that when I 21 Α No. 21 22 ioined the staff as to what procedures I would be 22 0 And I said treated. Have you ever performing. And I don't remember how we examined a woman who had a Prolift®? 23 23 specifically added on subsequent procedures, but it 24 24 Α would be my chairman. 25 25 In the course of your teaching, did you Q

Page 186 Page 188 train residents or fellows on the treatment of mesh resection? 1 1 2 complications? 2 To spare the patient another abdominal 3 3 A Specific to abdominal sacrocolpopexy and operation. 4 4 Q An abdominal operation is just a far more slings, yes. 5 5 serious, complicated operation than the vaginal Q And in terms of the abdominal sacrocolpopexy, what types of treatment did you 6 approach? 6 7 recommend or suggest to fellows or residents was 7 A It can be. 8 appropriate in the case of exposures or erosions? 8 Q As a practical matter, Doctor, if you've 9 A Depending on the size of the erosion, 9 not done a mesh resection, I assume you've done no 10 beginning with topical treatment, estrogen; if there 10 mesh removals? 11 appeared to be an active vaginitis going on, topical 11 A Except for TVT®. antibiotics; if that wasn't successful, then attempt 12 Q Except for the TVT®? 12 at mesh resection transvaginally; and if that wasn't 13 13 Α Correct. successful, then mesh resection abdominally. 14 14 Q And how many mesh removals have you done Q Do you agree that mesh exposures do not 15 15 with the TVT®? necessarily require any treatment? A That would have been at the Cleveland 16 16 MR. SLATER: Objection. Clinic. So, again, I can't give you a number, but I 17 17 18 You can answer. 18 would say less than five. THE WITNESS: I must say, my 19 Q When we were addressing the mesh 19 20 experience in treating patients with mesh erosion 20 resections, generally you would take the most conservative approach first to the treatment of that has fortunately been limited. I personally would 21 21 22 feel uncomfortable unless the patient was ready for 22 erosion? 23 frequent follow-up to just watch and wait. 23 A I personally don't like the word 24 BY MS. JONES: 24 "conservative" because it means so many things to so Q You said that you would -- I don't think 25 25 many people. Page 187 Page 189 you said this, but I interpreted this -- suggest 1 Would you choose the least invasive? 1 2 topical creams. That would be an estrogen cream? 2 It depends. I think if I saw a patient 3 3 with a very extensive erosion where I felt there was A Yes. a risk to her, then I don't know if I would feel 4 Q And did you find that the estrogen cream 4 5 was often sufficient to accomplish the healing? 5 comfortable wasting -- not wasting time but spending 6 A Again, my clinical experience in managing 6 time on something that wouldn't have a great chance 7 mesh complications like erosion is limited. 7 of success. Personally I'm not sure that estrogen has -- is 8 8 Q You told us, Doctor, that you were aware effective or whether it's passage of time. No one's 9 of a risk of mesh contraction. Did you ever have a studied the most effective way to manage mesh 10 patient that you treated for mesh contraction? 10 complications. A No. 11 11 12 Q When you say that your experience managing 12 You told us that you were aware of the mesh erosions is limited, do you have any idea how risk of infection associated with the use of mesh. 13 13 many mesh erosions you have treated? Did you ever have a patient that you treated for 14 14 15 A I would say a handful at most. 15 infection associated with mesh? Q Five? 16 16 Α No. 17 As you sit here today, do you remember 17 Α Probably less than five. 18 Q Have you ever done any mesh resections? 18 treating any patient who had mesh used in an A Only for a TVT®. abdominal sacrocolpopexy for any mesh-related 19 19 20 Q Never done a mesh resection for an 20 complication? abdominal sacrocolpopexy? 21 21 Α No. 22 Α 22 O Other than the TVT® that we talked about, 23 do you remember treating any patient at all for any Q Is there a reason, when you were talking 23 about doing mesh resections, that you would first mesh-related complication? 24 24 25 attempt a vaginal resection before an abdominal 25 A No.

Q Have you ever examined mesh removed from a patient that had been used to repair prolapse? A No. Q Am I correct that you've never then looked at mesh that's been removed under a microscope or held it in any way? A I have reviewed the histology slides 7 prepare for this case. I haven't handled it in my hands. Q Prior to being engaged as an expert 11 witness in this case, had you ever looked at 2 pathology slides on mesh; 2 pathology slides on mesh; 2 pathology of the training in the development of biomaterials see, 12 2 No. Q Prior to being engaged as an expert 15 witness in this case, had you ever held in your hand to examine any mesh removed from a patient of the transvaginal tape? A No. Q Prior to becoming involved in this 10 litigation, had you ever reviewed any 2 photomicrographs of mesh removed from a patient? A No. Q Prior to being involved and engaged as an expert 1 this case, had you ever seen any surgery or or beserved any surgery to remove mesh from a 2 Q Prior to being engaged as an expert 1 withing this case, had you ever seen any surgery or or beserved any surgery to remove mesh from a 2 Q Prior to being engaged as an expert 1 withing the properties of mesh; and 1 correct? A No. Q Prior to being engaged as an expert 1 withing the properties of the prostity of mesh; and 1 correct? A No. Q Prior to being engaged as an expert 1 withing the properties of the prostity of mesh; and 1 correct? A No. Q Prior to being engaged as an expert 1 was not in the prostity of mesh; and 1 correct? A No. Q Proor to being engaged as an expert 1 withing the properties of the prostity of mesh; and 1 correct? A No. Q Proor to being engaged as an expert 1 withing the properties of the prostity of mesh; and 1 correct? A No. Q Proor to being engaged as an expert 1 withing the properties of the prostity of mesh; and 1 correct? A No. Q Proor to being engaged as an expert 1 withing the properties of the prostity of mesh; and 1 correct? A No. Q Proor to being engaged as an expert 1 withing the properties of the prostity of mesh				
2 patient that had been used to repair prolapse? 3		Page 190		Page 192
A No. Q And I correct that you've never then looked at mesh that's been removed under a microscope or 6 held it in any way? A I have reviewed the histology slides 8 prepared for this case. I haven't handled it in my hands. Part of the being engaged as an expert with the single of the been in the ransvaginal tape? Prior to being engaged as an expert 1 than the transvaginal tape? Part of the been in this case, had you ever held in your hand to examine any mesh removed from a patient other to being engaged as an expert 2 than the transvaginal tape? A No. Prior to being involved in this 20 litigation, had you ever reviewed any 20 photomicrographs of mesh removed from a patient? A No. Prior to being involved and engaged as an expert 20 photomicrographs of mesh removed from a patient? A No. Prior to being involved and engaged as an expert 3 photomicrographs of mesh removed from a patient? A No. Page 191 Patient? A No. Page 191 Patient? A Now, Dr. Moalli at the University of 7 Pittsburgh is involved in studying mesh 4 characteristics. I am certainly not - at that time 5 I was not directly involved in tstudying mesh 4 characteristics. I am certainly not - at that time 5 I was not directly involved in the university of 7 Pittsburgh is involved in studying mesh 6 characteristics. I am certainly not - at that time 9 I was not directly involved in her research. I've been in her lab and she's shown me what she's doing. I'm have a broad on the porosity of mesh; am I correct? A Correct. Q You've never been engaged in any research on the porosity of mesh; am I correct? A Correct. Q You've never been engaged in any research on the porosity of mesh; am I correct? A Correct. Q You've never been engaged in any research on the porosity of mesh; am I correct? A Correct. Q You've never been engaged in any research on the porosity of mesh; am I correct? A Correct. Q You've never been engaged in any research on the porosity of mesh; am I correct? A Correct. Q You've never been engaged in any research on the porosity of mesh; am I corr	1	Q Have you ever examined mesh removed from a	1	polymer chemist, do you?
4 Diomaterials expert? 5 A No. Diomaterials expert in this case, had you ever held in tour hat the transvaginal tape? 1 A No. Prior to being engaged as an expert than the transvaginal tape? 2 A No. Prior to being involved in this litigation, had you ever reviewed any expert in this case, had you ever seen any surgery or observed any surgery to remove mesh from a patient? 2 A No. Prior to being involved and engaged as an expert than the transvaginal tape? 3 A No. Prior to being engaged as an expert than the transvaginal tape? 4 A No. Prior to being involved in this litigation, had you ever reviewed any expert in this case, had you ever seen any surgery or observed any surgery to remove mesh from a patient? 3 A No. Prior to being involved in this litigation, had you ever reviewed any expert in this case, had you ever seen any surgery or observed any surgery to remove mesh from a patient? 4 A No. Prior to being involved in this case, had you ever reviewed any expert in this case, had you ever seen any surgery or observed any surgery to remove mesh from a patient? 4 Prior to being involved in this case, had you ever reviewed any expert in this case, had you ever seen any surgery or observed any surgery to remove mesh from a patient? 4 Prior to being engaged as an expert with the development of biomaterials? 5 A No. Drior to being involved in this case, and you ever reviewed any surgery to remove mesh from a patient? 5 Page 191 Patient? A No. Drior to being involved in this case, had you ever seen any surgery or observed any surgery to remove mesh from a patient? 6 A No. Prior to being engaged as an expert with this case, had you ever performed any expert in this case, had you ever performed any expert in this case, had you ever performed any expert in this case, had you ever performed any expert in this case, had you ever performed any expert in this case, had you ever performed any expert in this case, had you ever performed any expert in this case, had you eve	2	patient that had been used to repair prolapse?	2	A No, I am not a polymer chemist.
5 At mesh that's been removed under a microscope or held it in any way? 7 A I have reviewed the histology slides 8 prepared for this case. I haven't handled it in my hands. 8 prepared for this case. I haven't handled it in my hands. 10 Q Prior to being engaged as an expert 11 witness in this case, had you ever looked at 12 pathology slides on mesh? 12 pathology slides on mesh? 13 A No. 14 Q Prior to being engaged as an expert 15 witness in this case, had you ever held in your hand to examine any mesh removed from a patient other 17 than the transvaginal tape? 15 witness in this case, had you ever held in your hand to examine any mesh removed from a patient other 17 than the transvaginal tape? 18 A No. 19 Q Prior to becoming involved in this 20 litigation, had you ever reviewed any 21 photomicrographs of mesh removed from a patient? 22 A No. 20 Q Prior to being involved and engaged as an expert witness in this case, had you ever seen any surgery or observed any surgery to remove mesh from a 22 perior to being involved and engaged as an expert 3 patient? 4 No. 20 Q Prior to being involved and engaged as an expert 4 witness in this case, had you ever seen any surgery or observed any surgery to remove mesh from a 25 laboratory studies on them? 1 patient? 4 No. 2 Q Prior to being engaged as an expert 4 witness in this case, had you ever performed any examination of the porosity of a mesh; 6 A Now, Dr. Moalli at the University of 7 Pittsburgh is involved in studying mesh 6 characteristics. I am certainly not - at that time 9 I was not directly involved in studying mesh 6 characteristics. I am certainly not - at that time 9 I was not directly involved in hardying mesh 6 characteristics. I am certainly not - at that time 9 I was not directly involved in studying mesh 6 characteristics of the been in her plab and she's shown me what she's doing 11 That would be the extent of my answer. 19 Q Vou've never been engaged in any research 19 Q Vou've never been engaged in any research 19 Q Vou've never been engaged in any res	3	A No.	3	Q And I take it that you're not a
6 held it in any way? 7 A I have reviewed the histology slides 8 prepared for this case. I haven't handled it in my 9 hands. 10 Q Prior to being engaged as an expert 11 witness in this case, had you ever looked at 12 pathology slides on mesh? 13 A No. 14 Q Prior to being engaged as an expert 15 witness in this case, had you ever held in your hand 16 to examine any mesh removed from a patient other 17 than the transvaginal tape? 18 A No. 19 Q Prior to becoming involved in this 10 Q Prior to being involved in this 10 Q Prior to being involved in this 11 bilitigation, had you ever reviewed any 12 photomicrographs of mesh removed from a patient? 12 A No. 13 Q Prior to being involved and engaged as an expert witness in this case, had you ever seen any surgery or observed any surgery to remove mesh from a 19 patient? 2 A No. 23 Q Prior to being involved and engaged as an expert witness in this case, had you ever seen any surgery or observed any surgery to remove mesh from a 10 patient? 2 A No. 3 Q Prior to being involved in this 2 patient? 2 A No. 3 Q Prior to being involved in this seen any surgery or observed any surgery to remove mesh from a 10 patient? 2 A No. 3 Q Prior to being involved in the research of Page 191 1 patient? 2 A No. 3 Q Prior to being involved in this seen any surgery or observed any surgery to remove mesh from a 10 patient? 2 A No. 3 Q Prior to being ingaged as an expert 4 witness in this case, had you ever performed any expert in this case, had you ever performed any examination of the porosity of a mesh? 3 C A Correct. 4 Witness in this case, had you ever performed any expert in this case, had you ever performed any expert in this case, had you ever seen any surgery to remove mesh? 4 A Correct. 5 Q Never done any suppressor meshes? 7 A Correct. 9 Q You've never been engaged in any research of the pores of mesh; an I correct? 14 A Correct. 15 Q You've never been engaged in any research of the pores of mesh; an I correct? 16 the pores of mesh; an I correct? 17 A Correct. 18 Q You've never been	4	Q Am I correct that you've never then looked	4	biomaterials expert?
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7 A I have reviewed the histology slides 9 prepared for this case. I haven't handled it in my 9 hands. 10 Q Prior to being engaged as an expert 11 witness in this case, had you ever looked at 12 pathology slides on mesh? 13 A No. 14 Q Prior to being engaged as an expert 15 witness in this case, had you ever held in your hand 16 to examine any mesh removed from a patient other 17 than the transvaginal tape? 17 than the transvaginal tape? 18 A No. 19 Q Prior to becoming involved in this 16 discussions and decisions surrounding biomaterials. 17 than the transvaginal tape? 19 Q Prior to becoming involved in this 16 discussions and decisions surrounding biomaterials. 18 as do n my background and my study in this case, 14 think I have a broad understanding of the input, 15 say, a medical director at Ethicon would give into 16 discussions and decisions surrounding biomaterials. 16 discussions and decisions surrounding biomaterials. 17 Q. That's not really what my question is, 18 Doctor. Let me ask this: You said based upon your 19 study in this case. Am I correct then that prior to 2 becoming engaged as an expert witness in this 21 patient? 19 patient? 19 patient? 19 patient? 19 patient? 19 patient? 10 patient? 19 patient? 10 patient? 11 patient? 11 patient? 11 patient? 11 patient? 11 patient? 12 patient? 12 patient? 12 patient? 13 patient? 14 patient prior to 20 patient? 15 patient? 15 patient? 15 patient? 16 patient prior to 20 patient? 16 patient prior to 20 patient? 17 patient? 18 patient? 19 pat	6	held it in any way?	_	
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9 BY MS. JONES: 10 Q Prior to being engaged as an expert 11 witness in this case, had you ever looked at 12 pathology slides on mesh? 13 A No. 14 Q Prior to being engaged as an expert 15 witness in this case, had you ever held in your hand 16 to examine any mesh removed from a patient other 17 than the transvaginal tape? 18 A No. 19 Q Prior to becoming involved in this 19 photomicrographs of mesh removed from a patient? 20 A No. 21 Q Prior to being involved and engaged as an expert 22 A No. 23 Q Prior to being involved and engaged as an expert witness in this case, had you ever seen any surgery or observed any surgery to remove mesh from a 19 patient? 10 patient? 11 patient? 12 A No. 13 Based on my background and wy study in this case, I a think I have a broad understanding of the input, 1 say, a medical director at Ethicon would give into 16 discussions and decisions surrounding biomaterials. 17 That have a broad understanding of the input, 1 say, a medical director at Ethicon would give into 16 discussions and decisions surrounding biomaterials. 18 A No. 18 Cotro. Let me ask this: You said based upon your 19 study in this case. Am I correct then that prior to 19 becoming engaged as an expert 19 patient? 19 patient? 20 Q Prior to being involved and engaged as an expert 20 part or being involved and engaged as an expert 20 part or being en	8		8	· · · · · · · · · · · · · · · · · · ·
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24 A Correct. 24 Q Well, have you ever held yourself out as a				
23 Q Tou Certainly don't hold yoursell out as a 23 psychiatrist!				
	/ 5			paycinadiat:

	Page 194		Page 196
1	A No.	1	federal regulations that pertain to devices?
2	Q Have you obtained any postgraduate	2	A I have reviewed some of them.
3	education in the field of psychiatry?	3	Q When did you review those?
4	A No.	4	A Do you mean a date or relative to this
5	Q Have you ever been granted privileges on	5	case?
6	staff at any hospital as a psychiatrist or for	6	Q Relative to this lawsuit.
7	psychiatry?	7	A Okay. Yes, relative to this lawsuit.
8	A No.	8	Q But you had never reviewed the FDA
9	Q You're certainly not Board-certified in	9	regulations prior to becoming engaged as an expert
10	psychiatry?	10	witness in this lawsuit?
11	A Correct.	11	A No.
12	Q It would also be true that you don't hold	12	Q I asked a very bad question. I think
13	yourself out as an infectious disease specialist?	13	we've got a double negative there.
14	MR. SLATER: Objection.	14	Had you ever reviewed the FDA regulations
15	You can answer.	15	pertaining to devices prior to becoming engaged as a
16	THE WITNESS: I am experienced in	16	witness in this case?
17	caring for the infectious diseases that occur in	17	A No.
18	gynecologic and urogynecologic practice.	18	Q Had you ever been involved in a clinical
19	BY MS. JONES:	19	trial designed to evaluate the safety and efficacy
20	Q There is a subspeciality that's recognized	20	of a medical device prior to becoming engaged in
21	for infectious diseases, isn't there?	21	this lawsuit?
22	A I don't know.	22	A Yes.
23	Q You've certainly not been Boarded as an	23	Q What device was that?
24		24	9
25	infectious disease specialist?	25	A Well, we hadn't decided. This was in the pelvic floor disorders network. We were interested
23	A No, I am not.	23	pelvic floor disorders fletwork. We were filterested
	Page 105		Page 107
1	Page 195	1	Page 197
1	Q And don't have any advanced training in	1	in studying mesh products. And that was at a time
2	Q And don't have any advanced training in the field of neurology?	2	in studying mesh products. And that was at a time when the products were rapidly changing, products
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Page 198 Page 200 director? BY MS. JONES: 1 1 2 A I felt that I had accomplished what I 2 Q Well, let me ask it this way: Would you wanted to accomplish. The clinical trials network ever perform a surgery on a patient who came to you 3 3 4 was functioning well. I was confident that it would 4 and said, Doctor, I've looked at the patient 5 5 continue without my leadership. And my health at brochure and I want to have a surgery involving this that time benefited from me reducing the intensity 6 device without first counseling with them? 6 7 of my workload and the amount of travel I was 7 A No. 8 8 required to do. O Did you use patient brochures with the 9 9 Q So am I correct, if we go back to where we TVT®? 10 started, that you were never involved in a clinical 10 A I did not supply patients with the patient 11 trial to evaluate the safety and efficacy of a 11 brochure. 12 device? 12 Q And that's because you considered them to be a marketing device? 13 A Correct. 13 A No. That's because if they were 14 Q Prior to being retained as an expert 14 witness in this lawsuit, had you ever reviewed the available, it would be someone else's job to make 15 15 them available to the patient, like the -patient brochure for Prolift®? 16 16 O I don't understand. 17 A No. 17 18 Q Had you reviewed the patient brochure for 18 A Like the nurse manager of the clinical area deciding what materials would be put out for any other product? 19 19 20 Specific to a medical device for prolapse? 20 patients' use. 21 21 Q That's something that was put out in your Q Right. facility and given to patients without the approval 22 A No. 22 of physicians? 23 Had you ever reviewed the patient brochure 23 Q A I don't know specifically. I wasn't for TVT®? 24 24 25 25 A I believe so. involved. Page 199 Page 201 Q Did you ever counsel with a patient about 1 Q When you said that you considered the 1 2 the patient brochure for the TVT®? patient brochures to be marketing devices, did you 2 ever use or make available a patient brochure to a 3 A I don't understand your question. 3 patient for any reason? Did you ever use the patient brochure for 4 4 5 5 the TVT® to counsel a patient? A For a commercial product? 6 6 Q Uh-huh. A No. 7 7 O You understand that patient brochures are A I did not personally do that, no. available through doctors to counsel patients? 8 Q Do you know whether in any institution 8 9 A Do I understand they're available? 9 with which you were associated the patient brochures 10 Q How do you understand that patients get 10 for devices were distributed to patients? the patient brochures? A I don't know. 11 11 12 Did you ever have a conversation with a 12 MR. SLATER: Objection to the form. patient about the contents of the patient brochure? 13 You can answer. 13 THE WITNESS: The hard copy, the 14 14 A Not that I recall. 15 little pamphlet? I would assume they usually pick 15 Q Do you remember whether or not there were that up in the doctor's office. patient brochures with Gynemesh® PS? 16 16 A Do I know if they existed? BY MS. JONES: 17 17 Q And they are designed to be used in 18 18 Q Uh-huh, or whether you used them. consultation with a physician, are they not? 19 A Prior to being involved --19 MR. SLATER: Objection. 20 Q Prior to being involved as an expert 20 21 You can answer. 21 witness here. 22 THE WITNESS: I don't believe it 22 A I do not know. 23 says -- I take that back. To my mind, they're a 23 Am I correct that prior to being involved 24 marketing device. 24 as an expert witness in this litigation, you have no 25 25 recollection of ever reviewing a patient brochure on

Page 202 Page 204 A Those are the brochures that we used from 1 any mesh product? 1 2 A With the patient you mean or just 2 the American College. 3 reviewing it for general reading? 3 Q You didn't develop a separate brochure on 4 O Just reviewing it. Do you remember ever 4 those conditions, for example, and those treatments 5 reading a patient brochure prior to being engaged in 5 and the complications that might be associated with 6 6 this litigation? it? 7 A No, I don't recall. 7 Α No. 8 8 O Do you ever remember walking into or 0 At any time, Doctor, while you were 9 looking at the brochures at Magee, for example, to 9 practicing before you left the NIH, did you ever 10 see what patient brochures were out there for the 10 take any sabbaticals? 11 patients to look at? 11 A I think when I first left the NIH, my 12 A No. 12 leave was described as a sabbatical with the 13 Q Have you ever used any materials put out 13 possibility I would return. And then I didn't return. Does that answer your question? 14 by a manufacturer to assist you in counseling a 14 Q Well, maybe. What did you do in that 15 patient? 15 sabbatical or did you do anything in that 16 A I don't recall. Using products was not a 16 17 big part of my practice. 17 sabbatical? 18 Q Well, let me ask you a little bit 18 A It was -- I didn't pursue another degree. differently. Sometimes there are brochures or It was a general term for not work -- you know, not 19 19 20 publications that may not deal specifically with the 20 being in that position any longer with the product but that may deal with the condition, pelvic 21 possibility that I was returning. 21 22 organ prolapse, for example. Do you ever remember 22 THE WITNESS: It is 5 o'clock. using any of those types of materials to counsel the 23 23 MR. SLATER: I think just go a couple 24 patients? 24 more minutes to finish this line of questioning and 25 A We had brochures that discussed conditions 25 that's okay. That's customary. Page 203 Page 205 that were prepared by the American College of 1 THE WITNESS: Okay. 1 2 2 Obstetricians and Gynecologists, and I would use BY MS. JONES: 3 those brochures in speaking with patients. 3 Q I asked you about what surgeries you were Q Other than the brochures put out by ACOG, permitted to perform or credentialed to perform. 4 4 5 did you use any other materials in counseling the 5 How did you go about determining which surgeries you 6 6 would seek credentialing in? patients? 7 7 A It depended on what surgeries I had been A Yes. We had prepared materials of our 8 8 experienced in during my training. own. 9 Q And did you, in fact, prepare materials of 9 Q Fair to say that you only sought your own with respect to prolapse? 10 credentialing with respect to the procedures that 10 A I think that was a joint effort with my you felt comfortable with? 11 11 12 colleagues in the division. 12 Α Yes. Q Where, at Magee or at Cleveland Clinic? 13 13 Do you know how many abdominal sacrocolpopexy cases you performed before you felt 14 Α In Cleveland. 14 15 Q Can you tell me what the form of that was? 15 proficient to do that surgery on your own? No, I don't remember. Was it just a typewritten description of prolapse or 16 16 did it cover the types of treatment and the 17 All of the surgeries that you performed 17 18 complications or was it more of a brochure? 18 involved dissection of tissues, did they not? A I can't recall all the details. What I A Is that a general question, every 19 19 recall is things like postoperative instructions, 20 20 surgery -how to reach your doctor, things like that. 21 It's just a general question. 21 Q Q You don't remember then something that was 22 22 Related to prolapse or every surgery at Α like a description of what prolapse is, what the --23 23 all? 24 Well, those are --24 Q Related to prolapse. 25 -- different treatments are? 25 Q Α Yes.

Page 206 Page 208 1 Q Did you use hydrodissection in your 1 2 I, KIMBERLY A. OVERWISE, a Certified 2 practice? Court Reporter and Notary Public of the State of New 3 MR. SLATER: Let me just stop here. Jersey, do hereby certify that prior to the commencement of the examination, ANNE M. WEBER, 4 It's 5 o'clock. It's after 5:00. We had planned to M.D., M.S., was duly sworn by me to testify to the 5 stop at 5:00. I wanted to let you go if you were truth, the whole truth and nothing but the truth. 5 finishing a line of questioning, but it seems that 6 I DO FURTHER CERTIFY that the 7 we're getting into something new now in terms of foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the 8 surgical techniques so I think it's a good stopping 7 time, place and on the date hereinbefore set forth, 9 point. I'm not going to tell her not to answer this to the best of my ability. question but --10 I DO FURTHER CERTIFY that I am MS. JONES: That's fine. 11 neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and 12 BY MS. JONES: that I am neither a relative nor employee of such 13 O If you'll answer this question and if attorney or counsel, and that I am not financially 11 interested in this action. 14 there's a follow-up or two, that would be fine, but 12 15 then we'll stop. 13 A We didn't call it hydrodissection. We KIMBERLY A. OVERWISE 16 14 CCR: 30X100224600 called it infiltration. We were not entering the 17 Dated: November 19, 2012 18 vesicovaginal and the rectovaginal spaces with the 15 16 infiltrate. 19 17 20 Q How did the infiltration differ from 18 19 hydrodissection? 21 20 22 A Hydrodissection, to my understanding, is a 21 technique in which fluid is injected into the 22 23 23 vesicovaginal and/or rectovaginal spaces. This is 24 24 unique to Prolift®. This is not the way standard 25 Page 207 Page 209 anterior and posterior colporrhaphy, for example, 1 **INSTRUCTIONS TO WITNESS** 1 2 are performed. Does that answer your question? 2 3 Q Well, I don't think so. I was asking you 3 Please read your deposition over carefully and make any necessary corrections. You should 4 about the difference between hydrodissection and the 4 5 infiltration that --5 state the reason in the appropriate space on the 6 A Okay. So hydrodissection, again, is in 6 errata sheet for any corrections that are made. 7 7 the vesicovaginal space. I'll just talk about that After doing so, please sign the errata 8 just for simplicity. It's the same for the 8 sheet and date it. 9 rectovaginal space, just the opposite, anterior to 9 You are signing same subject to the posterior. You understand. changes you have noted on the errata sheet, which 10 10 Infiltration when performing an anterior will be attached to your deposition. 11 11 12 colporrhaphy is the injection of the infiltrate into It is imperative that you return the 12 13 the layers of the vaginal wall. 13 original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition 14 Have you ever performed what you describe 14 as hydrodissection? 15 15 transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate 16 Α No. 16 17 MS. JONES: That's it. 17 and may be used in court. 18 MR. SLATER: See you tomorrow at 18 9:30. 19 19 20 20 MS. JONES: See you in the morning. (Witness excused.) 21 21 22 (Whereupon the deposition recessed at 22 23 5:08 p.m.) 23 24 24 25 25 CERTIFICATE

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1 2	ACKNOWLI	EDGMENT OF	DEPONENT	3					
6 7 8 9	I, ANNE N hereby certify that I 1-210, and that the of the answers give propounded, except form or substance, Errata Sheet.	same is a con n by me to th t for the corre	ne foregoing pages rrect transcription ne questions therei ections or changes	in					
13 14 15 16	ANNE M. WEBER, M.D., M.S. DATE Subscribed and sworn to before me this day of, 2012.								
19 20	My commission expi	ires:							
21 22 23 24 25	Notary Public		-						